Department of Health and Human Services

NATIONAL COMMITTEE ON

VITAL AND HEALTH STATISTICS

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CASET Associates, Ltd.
caset@caset.net

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P R O C E E D I N G S (9:05 a.m.)

Agenda Item: Welcome

DR. STEAD: Welcome, everybody. Let's start with our roll call, starting with members. I am Bill Stead. I'm chair of the Full Committee. I'm from Vanderbilt University. I have no conflicts.

MR. COUSSOULE: I'm Nick Coussoule, Blue Cross Blue Shield of Tennessee, member of the Full Committee, member of the Standards Subcommittee, member of the Privacy, Security, and Confidentiality Subcommittee, and I have no conflicts.

MS. GOSS: Alix Goss with Imprado, Division of DynaVet Solutions. I am a co-chair of the Standards Subcommittee, member of the Full Committee, member of Executive Committee, and I have no conflicts.

MR. LANDEN: Rich Landen, member of Full Committee, co-chair of Standards Subcommittee. No conflicts.

MS. STRICKLAND: Debra Strickland, Conduent Services. I'm a member of the Full Committee, member of the Standards Subcommittee, and I have no conflicts.

MR. PHILLIPS: Bob Phillips, executive director of the Center for Professionalism and Value in Health Care, member of the Full Committee, co-chair of the Population Health Subcommittee. No conflicts.

DR. CORNELIUS: Lew Cornelius, University of Georgia, member of the Full Committee and Population Health Subcommittee, no conflicts.

MS. LOVE: Denise Love, National Association of Health Data Organizations, member of the Standards Subcommittee and member of the Full Committee, no conflicts.

MR. PASQUALE: This is Frank Pasquale, from the University of Maryland, member of the full committee, chair of the privacy, confidentiality and security subcommittee. No conflicts.

MS. MONSON: Hi, I am Jacki Monson, Sutter Health, member of the full committee, member of the subcommittee privacy, security, confidentiality, and no conflicts.

MS. GOSS: So we do have a quorum, and now staff.

DR. ARNOLD: Hi, this is Sharon Arnold from HHS, the staff director of the committee.

MS. HINES: Rebecca Hines, I'm with CDC's National Center for Health Statistics, executive secretary and DFO for the committee.

MS. DOO: Lorraine Doo, staff to the standards subcommittee, with Centers for Medicare and Medicaid Services.

MS. SQUIRE: Marietta Squire, CDC, NCHS, and staff to the committee.

MS. HERRING: Good morning, Geanelle Herring, Centers for Medicare and Medicaid Services, staff to the standards subcommittee.

MS. GOSS: And then members of the public, please say good morning.

MS. MOSLEY: Good morning, Paula Mosley, Centers for Medicare and Medicaid Services.

MS. SCHULTZ: Hi, Kelley Schultz from AHIP.

MR. EISENSTOCK: Jay Eisenstock with WEDI.

MS. BLUM: Amy Blum, National Center for Health Statistics.

MR. FERGUSON: Jamie Ferguson, Kaiser Permanente.

MS. WEIKER: Margaret Weiker, NCPDP.

MS. PRELLWITZ: Leslie Prellwitz, American Medical Association.

MS. SHEPPARD: Cathy Sheppard, X12.

MR. FITZPATRICK: Andrew Fitzpatrick, with X12.

MS. KNAPP: Katie Knapp, Veterans Health Administration.

MS. GEARHART: Chris Gearhart, Centers for Medicare and Medicaid.

MR. CALLAWAY(?): Dan Callaway(?), Centers for Medicare and Medicaid Services.

MR. STELLAR: Charles Stellar, WEDI.

MS. NARCISI: Jean Narcisi, American Dental Association.

MS. KOCHER: Gail Kocher, Blue Cross Blue Shield Association.

MR. TENNANT: Rob Tennant, Medical Group Management Association.

MR. STRAUSS: Warren Strauss, Karna.

DR. STEAD: Welcome, everybody. Before I review the agenda, I just want to mention that since our last meeting, Linda Kloss's term expired. I think everybody will join me in thanking Linda for her steadfast leadership of the privacy work and her leadership also on the work we've done on terminology and vocabulary.

And this will be Bob Phillips' last meeting, and we want to also thank him for his leadership in the population health area and particularly around the challenges we face in access to data to support population health efforts, both national and local efforts. Thank you.

The agenda is jam packed. We really have a lot to do today, and I think it really shows the aggressive work the subcommittees have done since our June meeting. We'll start, Sharon Arnold will give us an update from the perspective of ASPE, and then we will have a block on our ICD-11 project, where we will update you on the expert

roundtable and then we will walk through, revise and take action on the research questions that came out of the roundtable, the communication topics, and the letter to the Secretary that has three recommendations about how to move forward with that work.

Then we will hear from Cathy Sheppard of X12 around the process changes they've been making that relate to our predictability roadmap work, and then the afternoon is really going to be a dive into the predictability roadmap and taking action, we hope, on a letter that has three pragmatic recommendations to the Secretary about how to begin to move forward, and then we're going to have several hours of work that continues our collaboration with ONC and that will include an expert panel on prior auth, and we'll close the day with a discussion on our ongoing, sort of next steps in our ongoing discussion with ONC around convergence.

Then we start back up at 8:30 in the morning. We have Tim Nolan from the Office of Civil Rights, joining us to update us on their perspective, and I think that will be helpful as we begin to think through our 2020 work plan. Then we're going to have Renee Gindi join us to brief us on the redesign of the National Center's Health U.S. Data Program to get our input into on what would be most helpful in that update.

Then an update on the federal data strategy from Margo Schwab of the Statistical and Science Policy Office, part of OMB. Then after lunch, we will have Frank walk us through the priorities from the perspective of the Privacy and Security and Confidentiality Subcommittee, and then we'll roll into our 2020 work discussion, public comment, and then close.

So that's the plan for the two days. It will be busy, and I think we have a remarkable set of people coming to talk to us. I think it will be extremely helpful.

So with that, I will turn it over to Sharon Arnold. Thank you.

Agenda Item: ASPE Update

DR. ARNOLD: Thank you very much. I want to start off by thanking Bob Phillips for his service on this committee. We really appreciate the work you've done on the population subcommittee and your leadership over the years on this committee, and your presence will be very much missed. So thank you so much for that.

We'd also like to thank Roland Thorp for his service on the committee. I know he's not here today, but in absentia we want to acknowledge and recognize his participation, as well.

On the positive side we have four new members that have been approved by the Secretary, and we're hoping

that they will join at the March committee meeting. They are Denise Chrysler, the director of the Network for Public Health Law, Jim Cimino, professor and director Informatics Institute, the University of Alabama at Birmingham, Melissa Goldstein, associate professor, Milken Institute of Public Health at GW University, and Margaret Skurka, professor emeritus of College of Health and Human Services University of Indiana University Northwest. So we very much look forward to welcoming these new members at the March meeting.

Four members have been renewed for a four-year term, Nick, Rich Landen, Jacki Monson and Debra Strickland. So we're very happy to have you continue with us. This means we will have a complement of 14 members come March. So we'll be still four short of the total of 18. We're in the process of thinking about the expertise needed for new members, and one these vacancies is appointed by the Senate, but the rest are appointed by the Secretary, and if you have any suggestions for us or any ideas for us, please let me know, as we're actively soliciting recommendations for potential members.

So I know I usually kind of talk about the priorities of the department, and those priorities are still the ones that I mentioned before. Value-based purchasing is clearly one. Dealing with the opioid crisis

is another, and then trying to reduce the high cost of drugs are the real three priorities that we're facing in the department, and there's a lot of effort being devoted to those priorities across the department.

We're also, at least kind of the data folks in the department, very focused on implementation of the evidence act, and we've been working very closely with OMB, in the development of guidance. There are a number of working groups happening at OMB, coming out with a stream of guidance. Internally, we are thinking about the development of evidence plans. So each department is now coming up with kind of evaluation plans, or evidence-based plans, to identify the most important questions, and hopefully the data strategy will tie to the important questions within each department. At least that's the way we'd like to think it happens.

At the same time, we are assessing our data resources, what's currently made available publicly, what might be made available publicly. What are those gaps? What are the activities we need to undertake to make those data ready for public access in terms of documentation? Any editing for kind of privacy, or other things. So it's a huge lift we're trying to figure out how to stage this. So there is a lot of work going on.

We've organized ourselves in a number of ways in the department to do this. We've had a data council, an HHS data council, for quite a number of years. We are kind of reformulating that to be very focused on implementation of the evidence act. We have a much newer evidence and evaluation council to kind of think about that and of the requirements, and kind of those councils will be providing analysis and recommendations up to a leadership council within HHS for implementation, and while we get ourselves together, we're waiting for OMB to provide us guidance. So a lot of activity going on in that area.

The department was tasked with naming three officials to implement the evidence act. We have evaluation official, and the ASPE is the evaluation official. So right now, Brenda Destro is in that role and we're staffing her. There's a chief data officer, Jose Arrieta, who is our chief information officer, is acting in that role temporarily while we look to recruit another individual for that role, and there is a statistical official, and Jennifer Madans, who is the acting director of NCHS, is filling that role now. The director of NCHS will be the statistical official for the department.

Let's see, as you may know, we do not yet have a 2020 budget. We have a CR in place for a bit of time. I think folks are very hopeful we'll have an extension of the

CR and we'll have a budget before the end of the year, and we're keeping our fingers crossed on that front.

So I think that's all I have right now. Happy to answer any questions.

DR. STEAD: Questions for Sharon?

(No response.)

Thank you.

DR. ARNOLD: Thank you very much. I apologize that I won't be here for the majority of the day today. I have other conflicts. But I hope to be back tomorrow for the majority of the day.

DR. STEAD: Thank you very much. Thank you most especially for the good news on the new members. Thank you.

Agenda Item: ICD-11 Follow-up and Action

DR. STEAD: Okay, let's roll forward into ICD-11. And I will turn the mic over to Rich Landen, who is going to lead this journey.

MR. LANDEN: Setting the context, as you will remember from our last meeting, World Health Assembly, World Health Organization just approved ICD-11 at the end of May. ICD-11 will replace ICD-10 in part, we will talk about that in a little more detail later. There are two main aspects of it. One is mortality data and the other is morbidity data. Two different paths, this committee has to

wrestle with both of them in terms of fulfilling our charge to advise the Secretary toward an adoption path on both.

The mortality adoption is not discretionary. It's part and parcel of the country's participation in the World Health Assembly. The morbidity aspect is a matter of rulemaking, as ICD is one of the named medical code sets under HIPAA. And again, to the charge to this committee, we must render advice to the Secretary.

So in general we'll be taking a look at both of those, and our advice at this stage is that we need three things. The first thing is a research into what is ICD-11 and its fitness of use for the purposes to which this country puts the ICD. The second is a communications plan based on our country's experience with the transition between ICD-9 and ICD-10. We ran into some issues. It was a prolonged and costly implementation.

And so we're hoping that the advice we're rendering will take advantage of the lessons learned and will make this a better informed, smoother, more efficient process. And by the way, part of the recommendations will be making, need to make determinations about timeframes for adoption. Then the third thing deals with some copyright issues that are not controversial for the doctors, but it's a different question for this country, vis-a-vis its relationship with the World Health Organization.

So with that as an overview, lets walk through the slides. This slide, most of the slides you will have seen. These are a repeat from what we presented as part of our scoping and go forward path at our last full meeting. So I will go through these rather quickly, just as a refresher and for those in the room and those listening in on the webcast who may not have seen these or remember them from June. So we have, NCVHS has a specific charge related to data standards that is study the issues related to adoption of uniform data standards and patient medical record information and to advise the department on health data collection needs.

As part of that charge, we as NCVHS have had a longstanding program around health terminology and vocabularies. We've taken a look at health terminology and vocabulary in the United States and made some recommendations to the Secretary about the changing environment and the implications for timing an approach to health terminology vocabulary standards adoption, looked at the needs, opportunities and problems with the development dissemination maintenance and adoption of terminologies and vocabulary standards, and we've looked at actions that HHS might take to improve the situation.

Strategic goals. Assess, identify recommend.

This a pictorial timeline of the project. As you see, it started in early 2017 and continues to present day. In July --

DR. STEAD: I'll make just one point. This has been a two-year journey, if you go back one slide. I just want everybody to know, from our perch, if we can take action on the letter and the questions and communication plan today, then we step out of this until HHS does something. We will have framed how the department can actually approach this problem. And then until the results from that come back, we go on to other things. So this, although this has been a long journey over the last couple of years, our intent is to bring this phase of the journey to closure today, to free the bandwidth of the committee to deal with other standards issues.

MR. LANDEN: Assuming that the committee's concurrence on the basic recommendations to the Secretary, after the Secretary takes action based on those recommendations, then, as Bill said, at some future date, there will be a lot more work for the committee, but for the immediate future, our view of our path forward has a fairly prolonged hiatus while some of this research is done. And then based on the research, as Sharon was talking about, a lot of evidence-based decision-making,

when we get the evidence back in, then we will determine our next steps.

So starting in last year, July 2018, we did an expert consensus into an environmental scan in the terminologies and vocabulary area and got a very good picture what that landscape looked like. Also, identified gaps in coverage and areas of redundancy and overlap.

Near term opportunities identified. Again, this goes back a year, principles to guide adoption, principles for updating, including the curation, important point there is backward compatibility, transparency about what's changed. Publish cadence reflecting explicit cost and benefit. Dissemination, focus on electronic including implementation and mapping tools, minimizing cost and license barriers. Those were some of the key concepts identified a year ago.

Application of some of the principles. We needed to conduct research to understand the benefit and cost, and when we use the term benefit and cost, we're talking more globally; we're not talking about a cost benefit analysis as an accountant perhaps would think of it. It's not just the dollars and cents. It's overall value, both dollar and cents, but also policy value and other less fungible, less tangible quantifications that just add value to the ecosystem in this country and ultimately benefit patients

but also with benefit to the providers and all the cast of characters that make up our healthcare ecosystem.

So conduct research to understand benefit and cost of moving to a new version. Evaluate, this a key point. Evaluate whether a clinical modification to ICD-11 is necessary, or whether the intended design of ICD-11, which includes addition of morbidity is adequate for U.S. uses or can be supplemented through other standards, in lieu of developing a full U.S. clinical modification as we had with ICD-10 and ICD-9.

Also, the prior recommendation address simplifying the rulemaking process around these updates of terminologies and vocabularies and description of the pathway that balances priorities and communicate the pathway clearly to industry stakeholders. Again, multi-trillion-dollar economy in U.S. healthcare. A lot of different stakeholders, a lot of different perspectives, a lot of different economic models. Important to communicate to the entire industry, including those primarily, not only including those primarily affected, but downstream users, who have their own obligations and responsibilities that are also then impacted by the choices that the primary data collectors are faced with, as well.

Current project goals. Foster early stakeholder engagement and industry communications. Again, this is

leveraging the experience that we had fairly recently with the transition from ICD-9 to ICD-10. And develop recommendations for the Secretary regarding a pathway to ICD-11 that incorporates the simplified regulatory process that we've already advised the Secretary about. To evaluate the benefits, costs, problems coming from the transition from ICD-10. Evaluate ICD-11 against the criteria that this committee has recommended. Specifically evaluate moving the country to ICD-11 for mortality, and then separate but parallel, evaluate moving to ICD-11 for morbidity.

First phase of the project was a letter to the Secretary. We completed that this past February. Encourage regulatory simplification to remove the requirement of formal rulemaking for ICD versions with three recommendations.

Again, for background, ICD requires full rulemaking. Other medical code sets that are included in the HIPAA umbrella do not require new rule making to advance a version. That happens as part of regular maintenance. Part one, HHS should use subregulatory processes to make version updates to ICD in the same way it handles updates to all the other named HIPAA code set standards. Two, HHS should invest now in a project to evaluate ICD-11 and develop a plan that will enable a

smooth and transparent transition from ICD-10 to ICD-11 at the optimal time. Notice we're not defining the time, that our definition of the timeline or pathway is dependent on the results or research that we hopefully will be recommending.

Three, HHS should clarify that ICD-10 PCS procedure coding system is completely separate and independent from ICD-10 and will not be updated, does not need to be updated, with the transition from ICD-10 to ICD-11. Again, an important component of the communication plans.

Phase 2. Produce a mini environmental scan. What have we learned from the transition in the past, what's the historical timeline, what's the impact data? Literature review and summary of findings, synthesis of costs, benefits of the transition? And we have lots of help in this endeavor. National Center for Health Statistics, CMS, National Library of Medicine, Veterans Affairs, and the Vanderbilt University Medical Center team.

Identify research questions and draft letter. This is the stage that we are at now and will be considering this morning. Identify research questions to inform the evaluation of benefit and cost of the transition to 11 for both morbidity and mortality. Appreciate that stakeholders and processes for these two aspects differ

significantly. Develop a letter to the Secretary with questions developed at the August expert roundtable meeting for action today.

So we had the expert roundtable meeting this past August, and these were the meeting objectives: a shared understanding of lessons learned from ICD-10 and ICD-11 transition. The distinctions, the differences between 10 and 11, reach consensus on the research questions broadly to be answered to inform the evaluation of ICD-11 for mortality and morbidity, and to identify the impacts should this country decide not to move to ICD-11 for morbidity. Again, mortality, nondiscretionary. And third, identify key topics and messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

So we held the expert roundtable in August. It was a very productive session, a lot of good discussion. We had people who were eminently knowledgeable, both in breadth and depth. So these following slides just kind of highlight some of the takeaways from that session, and as we get then into the letter of recommendation that's in the agenda book, it's a draft, and as we get to the supporting recommendations on the research and the communication, you will see these takeaways reflected and distilled down into some pretty concise language.

DR. STEAD: Just to emphasize, standards subcommittee did a wonderful job putting all the right people in the room. We had technical experts in the underpinnings of ICD-11 and the related clinical HIPAA related standards, and we had experts in both the coding of mortality and the use of mortality and in each of the key stakeholder groups, that deal with ICD-10-CM, the morbidity version. So it really was amazing and many of them had the fortitude to be there a year ago, and many members of the full committee in addition to the subcommittee were there. So this really has been a remarkable effort at identifying alinement and what the key messaging really is. So my hat's off to the standards subcommittee.

MR. LANDEN: Getting back to the takeaways, first, ICD-11 is believed to be a major advance. ICD-11 is based on current medical knowledge, while ICD-10 effectively was built around 1980s era medical knowledge. So the supporting documents that were at the roundtable, and you've seen, the committee members have seen, before, shows a very, very lengthy period covering almost three decades between the time ICD-10 was first formulated and the time we adopted it, in 2015 in this country.

So even though it's relatively newly adopted for us on the morbidity side, it is still a 30-plus-year-old set of knowledge and vocabularies. ICD-11 was designed

from the get-go to work in today's electronic world with computers and computer assisted processing. Better support for interoperability, which this country has been moving toward for at least 10 years as a primary policy goal for the country, and having ICD-11, having an extensibility structure that supports local data priorities. Again, that's important because, extensibility allows an organized way for the vocabulary to harness local needs that are not shared globally. Again, extensibility has its own issues, but rather than baking a lot of the codes into the root vocabulary, it's allowed extensions that will make the local management a little bit easier and the local adoption less complex.

DR. STEAD: Just to be clear, the word local, as Rich is using it, means local to the different countries. It doesn't mean local to the community level the way we've been using it in some of our pop health work. So just to be clear, it's referring to the intent of ICD. One of the intents behind ICD-11 is that there should be less need for national modifications of any sort. That's their intent. One of the things the research will have to validate is the degree to which that is or is not true for U.S. use cases.

DR. PHILLIPS: Just curious. Who manages that process? Who would manage that for the United States, for example? The local extensions?

MR. LANDEN: That is one of the things we need a little bit more research on is to flesh that out. In theory, it would be NCHS.

DR. STEAD: I think the WHO at this juncture has a process. NCHS and other key pieces of the United States participate in that process. As NCHS has now, for updates to 10-CM, we're assuming there would be a U.S. process that fed in in some way. But that would be, figuring that out is part of the research, as you'll see when we get to those questions.

MR. LANDEN: There is a U.S. coordinating committee. Thank you, Rebecca. And that function will continue, and as Bill said, in part it's local, meaning United States, and in part it needs to be tied in with the maintenance structure that World Health Organization has. This is something new that's, the framework is there, but it's not a tried framework yet.

Back to the slides, the last bullet on this slide. Important to note that the World Health Organization will no longer be maintaining or updating ICD-10. Again, differentiation between ICD-10 itself and the

U.S. clinical modification, for which the maintenance committee does remain in effect.

More takeaways. The U.S. adoption for mortality is nondiscretionary. It's only the timing that this country needs to decide, and impacting the timing needs is the federal and state agency preparations that will be required for the transition. On the other hand, U.S. adoption for morbidity, as I described earlier, is a HIPAA medical code set. We have to establish the fitness for U.S. use. We have to make a determination about whether or not a U.S. clinical modification will be necessary. We must demonstrate the value of the adoption as a prerequisite for HHS rulemaking. The standards organizations must understand and prepare for incorporation for ICD-11 into their standards.

More takeaways. ICD-10 transition, implementation, lessons learned. Number one was lack of evidence-based knowledge resulted in conflicting expectations, both positive and negative, around cost and value. So there was a lot of disagreement about what the value is and what the value was, and what the costs were. The prolonged debate made the transition from ICD-9 very lengthy, very uncertain, very inefficient, and wastefully expensive. Lack of thorough preparation and testing

resulted in problematic adoption, especially in downstream users.

For instance, the state databases and some of the data registries, who, even after ICD-10 was adopted, those data warehouses were not prepared to take in the new data feeds and merge them with their existing ICD-9 based data. Then finally, a well-reasoned approach to research and communications should pay large dividends in achieving a less contentious and less problematic and more efficient adoption of ICD-11.

So why are we recommending a research agenda? Key use cases will have to be developed to demonstrate how well-suited ICD-11 is to support the uses we put the code to here in the United States. Can ICD-11 fully support morbidity classification in the United States without the clinical modification that we had for 9 and 10? What are the cost benefit estimates? What are the opportunity costs of alternative timelines for transitioning from 10 to 11? What is the impact of changes in ICD-11's code structure in different environments and on other health information standards designated in regulations under HIPAA or promoting interoperability?

More on the research agenda. What is the quality of WHO mappings of ICD-10 to ICD-11 for U.S. use cases? What is the potential of ICD-11 to support greater

convergence of clinical and administrative standards for morbidity? And we need greater insight to how to derive benefit from the greater computer processing capability that is designed into ICD-11.

Communications plan. Every healthcare stakeholder was impacted to some degree by the transition from 9 to 10. We need a trusted source of truth for the industry, and that would have helped to mitigate inconsistent messaging and misinformation that we experienced in the transition from 9 to 10. Healthcare organizations, because of the recent transition from 9 to 10, learned a great deal about succeeding with this complex type of change, and these lessons can be strategically leveraged for preparation for the transition to ICD-11.

Open it up for questions and discussion and then we will get into looking at the recommendations.

Bill?

DR. STEAD: What we are really going to do is let you put up first the research questions, then the communications plan, and then the letter, and to go through them paragraph by paragraph, if not line by line. We've also taken the expert roundtable meeting summary, and that was sent, not only to the full committee, but also to all of the participants in the roundtable. They had time to provide comment. We got many excellent comments. They

were incorporated in the version you have the link to, in the agenda book so that version of the meeting summary, reflects all of that input.

PARTICIPANT: And it's on the web site.

DR. STEAD: We did the same thing with the research and questions and communication plan. Once the standards committee signed off on the first draft, that went out to all of the participants in the roundtable. We got their comments. It was incorporated back and that went back to the standards subcommittee. And that's what we sent out and that's what we will be reviewing here. So this has been through broad-based vetting at this juncture.

DR. LANDEN: Any questions from the committee members on the phone about the lead-in that we just went over?

DR. PASQUALE: No, that was very clear, thank you.

DR. STEAD: Thanks, Frank.

While we're waiting, we have written the research questions and the communication plan, so that they can each stand alone. So each actually has a short introduction that tries to put them in context. So you'll see a little bit of redundancy in this, but that's the logic behind it.

MR. LANDEN: All right, to understand the context in the, we're looking at the research agenda here. This will be an attachment. Structurally, this will be an

attachment to the letter. The letter itself will take the highlights, put it in the letter. And then when we get into the communications plan, likewise, what you'll be seeing on the screen will be an attachment to the letter with the highlights incorporated into the letter.

So let's just walk down through this. So the first paragraph just gives kind of the background, where we are.

DR. STEAD: And again a key point in that paragraph is U.S. experts have been heavily involved in the development of ICD-11. The key point of the second paragraph is the fact that previous versions of ICD were built for a paper world. They were, in essence, lists of classification codes. And they would be updated once a decade.

ICD-11 is completely restructured to basically have a foundation that allows you to, if you will, extract linear classifications. It also allows you to relate the other terminologies, such as the ones that are in our clinical tool sets. So it's a fundamentally different approach. It's intended to be incrementally updated and, therefore, hopefully to get out of these massive updates.

Just go back to this bullet. Just make sure people, because this was the shortest comparison between 10 and 11 that we can develop. And it's now been heavily

vetted. We try to keep it up a level. But if there is anything there that is confusing or gives you heartburn, let us know.

MS. HINES: Folks on the phone, just jump in at any time, we're basically in working session mode.

DR. PHILLIPS: The purpose of specific classifications may be arrived at computationally. What does that mean?

DR. STEAD: If you go back up, so, the digital representation of health terms, classes, and the relationship between terms and classes, is in the foundation. You therefore can derive the classification and you can emphasize different classes and relationships as you do that. So you do not have to end up with a single classification to have ones that work together.

DR. PHILLIPS: Does it also support research that way that you're creating taxonomies of how things relate to each other, how these classifications may be separate or starting to coalesce, or --

DR. STEAD: Well, yes, and it's intended to represent the reality of today's biological in practice where it takes a network of relationships to represent anything, granted accurately at a granular level. This is designed to allow you to do that. We're trying to be very careful, between what is the intent, what's intended to be

designed in and what it actually is, because the research has to resolve that. It is, I won't go into some of the sausage-making.

MR. LANDEN: Yeah, also to note, the final bullet on the bottom right, includes tools and services to support implementation. That again was something WHO and us learned from ICD-10, that implementers need a lot more support than was baked into ICD-10. So more maps, more granularity in the maps, more support tools, more references, more definitions. And the process that WHO used in this was kind of a wiki concept, so WHO does make available a lot more of the background information on its website for those that really want to understand why the process, the sausage-making process, as Bill described it, resulted and what went into and what was approved in ICD-11.

DR. STEAD: The other thing we should highlight is the third bullet in 10 and the third bullet in 11, because these are hard for people that don't live in this space. So the ICD-10 codes had a single code to capture the multiple evidence of a condition, and that code fit or it didn't fit. And if it didn't fit and you were trying to evolve, you actually added another code that might have 75 percent of it the same, and one thing different. ICD-11 allows for, and that approach that's done in 10 and

everything before it, is called precoordinating. You precoordinate everything into a single code.

With ICD-11, you post-coordinate. I.e. when you're at your EHR or whatever and recording something, you cluster the stem codes you need, the base concepts and the extensions if needed, so like, left and right would be extensions, not stems. And that reduces the number of codes you need in one way of thinking because you are assembling things to represent the various combinations. It obviously can increase the complexity of the data capture. You can now begin to see why the research is going to be important.

DR. PHILLIPS: I am struggling because I wear a research hat, and I wear a clinical hat. And I'm -- whose cost and whose benefits are always the important question when you are looking at this. You know, which is the transition from 9 to 10, it required in my own clinic a pretty substantial overhaul of our EHR, which we bore the cost for.

And it translated into cost to us in terms of the data capture at the point of care, because you would click one thing, and then suddenly you had to click several other things to add specificity that may or may not matter to us. So, I know you've had many experts in these conversations,

but how that benefits the clinician and the patient, the front line, is going to be critical to be clear about.

DR. STEAD: Bear with us. You'll see two things we are trying to do. The whole first category research question is what are the use cases. Then further down in the research questions you'll see that really broken out. So make sure we got it right as we go down there. It's absolutely critical that we get that right.

MR. LANDEN: Your question goes back to what I was trying to describe earlier when talking about cost and benefit, not necessarily from an accounting value, because you're absolutely right, the costs of implementation were unevenly distributed relative to the value. We as a country understand that. There's no way around that, and it's part of the regulatory process under HIPAA to make sure that at a national level that the value is worth the cost. That value equation really doesn't make whole any of the actors in the ecosystem who have a disproportionate burden.

So there are those who derive value from a -- let's refer to it generally as a better classification, coding system -- they don't necessarily bear the cost of the data collection. But as a country, which is the level we as the NCVHS are dealing with, we have to be sure we have the research in hand that demonstrates the value

exceeds the cost to the country. Really good question, obviously, all of us will keep our eyes on that.

Again, going back to the bifurcation, we've got the mortality reporting, cause of death. Cause of death reporting is led by the National Center for Health Statistics, and the reporting of the death certificates is a state activity, but those states report in plain language. The death reports do not code cause of death in ICD. That coding is done by NCHS, and then where the states do get involved, is NCHS reports back to the state using the codified data. So even though the states and coroners and funeral home directors do not now and will not under 11 be required to code in ICD-11, those who use the information coming out from NCHS will have the transition from 10 to 11.

We divided this into different areas. First, to research, applied to both mortality and morbidity. Third is specific to mortality, and fourth, morbidity. So the common questions -- here's the perspectives we need to come from: healthcare delivery, coverage and payment, pop health and public health, safety and safely -- safety, we did a lot of conversation about that. It's not just patient safety, but there are other safety aspects throughout the system. And then research and evaluation perspectives.

Then for each of those perspectives, which uses are appropriate for ICD-11, and which not? So on the clinical, what level of detail is needed for good clinical documentation and support clinical decision-making? Are there differences by specialty or type of practice?

DR. STEAD: So the way we in the end decided to deal with complexity is let's make the first question, do the research to identify the perspectives, and in essence come up with the key use cases. Then you're going to apply that to every question downstream, because you'll end up needing a matrix of answers. This is that complex.

One of the key things around some of these sub-bullets on the second question is, we need to get the data to let us know when would we be trying to use ICD-10, and when we be trying to code in some of the other HIPAA-related standards, like SNOMED. We don't need to code things both ways. So we actually need to know what we would be doing with each to know how to evaluate the fitness for ICD-11, for its part, but then we also need to be able to communicate that clearly to all the stakeholders who will have to implement this. So that's really what these first pieces are trying to do.

DR. PHILLIPS: I'm sorry to keep weighing in, but on the perspective side -- Sharon, I'm so grateful that you brought up the evidence-based policymaking as a focus for

HHS on its priorities. Is that embedded in here? Is this one of the perspectives that the evidence-based policymaking, or maybe that's far too specific -- but to inform policymaking? Because that brings with it a cost issue.

DR. ARNOLD: I'm not sure that the kind of policymaking, as a, wouldn't be covered by the other five categories. Delivery, payment, population, public health. Those are really the issues that HHS is focused on. I'm not sure there are other questions that couldn't be classified under those.

MR. LANDEN: Bob, I think in part, this whole process is designed to be an exercise in evidence-based policymaking, but specifically to your question I think the only place that comes in is 1-C. It's just unstated, but it's assumed under the population and public health bullet.

Later, you'll see some more detailed examples that specifically talk about policymaking at both the federal and state level and having evidence to inform the decisionmakers.

DR. PHILLIPS: When you're coding a billion visits a year, does ICD-11 help us with policymaking? And I guess as long as that's implicit under these five categories, that's fine.

MR. LANDEN: Roman II, research, evaluate content consistency and stability of ICD-11. While we have confidence in the work of World Health Organization, we do need, we are recommending, if you agree, we are recommending independent U.S. verification and validation of ICD-11 content and methodologies for post-coordination and curation. Look at the mapping, ICD-10 to 11, 11 back to 10. Important to note that only about a third of the codes have one-to-one mappings. So when you have many-to-many and one-to-many, that works fine the first iteration, but if you need to map that back you can't do it anymore, so what's the impact there? Again, understanding that no system is perfect, where nothing we could do would eliminate one-to-many and many-to-one, but is it good enough for our uses?

Content methodologies, some representative questions. Does ICD-11 have redundancy? Does it have ambiguity? If the name of the code changes are the meanings changed? Does ICD-11 delete codes? If so, what's the process for handling with regard to preexisting data? If the classification changed, does the code change? Just a lot of questions about the details of how this works, so when we get into an implementation, all the little things that we stumble over, we know how they're going to be resolved.

Denise?

MS. LOVE: I'm back up on an earlier bullet. On the 33 percent, I know I've heard that, but did WHO come with that metric, that mapping? Where's that number coming from?

MR. LANDEN: I believe so, but if there's somebody here that can validate that. I believe it was WHO that did that as part of the documentation that they provided.

DR. STEAD: I think it was also done as part of the work that Olivier Bodenreider did at the NLM, that was presented at the workshop. What we'll need to do is, we've got Olivier's PowerPoint, we can walk you back through. The NLM did the first round of research to help us get ready for the roundtable. This was one of the things. They went through the details of what mapped and didn't map, and gave specific examples both ways. And then Chris Chute went through the comparison to SNOMED. So that data, we've got that on the website.

MS. LOVE: I don't think it's relevant to this letter, it's just inquiring minds.

MR. LANDEN: I am also reacting because remembering back to ICD-10, I thought the 33 percent was high. I though one-to-one mappings were really rare when I had to be doing some of those mappings.

DR. STEAD: Just from an agenda process point of view, let us have discussion, but I want to make sure we get through research before the 10:30 break. I think we can handle communication and the letter after the break if we need to.

MR. LANDEN: Sounds good. Number two on the slide, then, evaluating mechanisms of covering content gaps. How do we handle mandated post-coordinated extensions? Again, remember there's a base code and there's an extension, and that differs from what's in ICD-10. How do we add new base concepts?

Again, as Bill said earlier, this is designed for iterative updating and additions. Changes and keeping it current, rather than replacing it in 15 years with another new version. Leveraging related terminologies for domain-specific concepts, such as signs, symptoms, medications, toxins, devices. Alternative approaches to accommodating regional and urgent codes, stem cells, without compromising consistency. Again, goes to how do we keep it current, and meeting the needs of the use cases.

Research to inform HHS decisions about process and timeline for implementing for mortality. So again, specific to mortality, put morbidity aside for the moment, compare coding quality project cost and time required to implement automated ICD-11 coding. Automated coding is

what NCHS uses now with 10. That software would need to be totally upgraded or rewritten to handle 11. Natural language processing. And it gets into some of the details about how do you train the new software for natural language processing.

Number two, evaluate the cost and benefits of transitioning from 10 to 11 for mortality in three years, versus six years.

Denise?

MS. LOVE: Are you going through each bullet, because I have a comment on two. It's just that A-2, under 2-A-2, states for database conversions, but they're also, in my notes, when I read that, it said, I thought you're going to have to change the laws and regulations, too. Maybe that's implied. Because many of the collections --

MR. LANDEN: Let's tease that out a little bit. Again, with mortality the states are not reporting the ICD codes. They're consuming the ICD codes generated by NCHS. We're --

MS. LOVE: I am thinking of hospital. I'm just thinking through PHC4 would have to maybe change their laws or regs, probably regs, to accommodate the standard. And it's a minor thing, I don't want to make more of it than it is. Maybe not for mortality.

PARTICIPANT: It's morbidity.

MR. LANDEN: This section is mortality only.

Okay, 4 talks about morbidity only, not mortality. Number one, do we or do we not need a U.S. clinical modification? And unknown, of course, is if we do decide we need a clinical modification, how long will that development take? And that will dramatically impact the potential adoption timelines.

Evaluate fitness of ICD-11 for morbidity to contribute to convergence of clinical, social, and administrative health information standards, EHRs, and related software. Again, EHRs, there's a clinical aspect to it and there's a payment and processing and insurance aspect to it. EHRs, depending on your vendor, may have some of the nonclinical functions integrated, otherwise you're talking about separate software for practice management or hospital administrative, hospital billing systems.

Can ICD coding be implemented as a computable service on top of standardized clinical statements captured by the EHR using the ONC is promoting interoperability standards? And cost and benefits.

Questions there?

DR. STEAD: Question 3 is where we tried to get at the part you were raising, Bob.

MR. LANDEN: So evaluate ICD on burden, efficiency, workflow -- the term workflow came up very, very frequently in all sorts of our conversations around the ICD. And workflows, no matter what type of organization you work for, that needs to be taken into consideration, needs to be taken into consideration with the standards development. You'll see that theme picked up as we get into the predictability roadmap.

How will ICD change what's happening now? Again, the question of who bears the burden, who gets the benefit, and how does that all sort out at the national adoption level? What tools are capable with ICD-11, what methods of analysis are needed to reduce workflow burden and improve documentation quality? And that's both software and human factors.

Evaluate alternative approaches to training and ongoing support. Again, we had a lot of testimony from the coding community. This will change the nature of the -- has the potential of changing the nature and role of some of the coding techniques and skillsets that are in place now. Evaluate the interrelationships between ICD-11 and other types of standards. Technical changes in some of the transaction standards -- again, for the example, the X12.

Alix?

MS. GOSS: We're very specific in that list to our standards community. It seems odd that HL7 is not listed.

PARTICIPANT: Would you like it added?

MS. GOSS: Sure.

DR. PHILLIPS: From a primary care perspective, it's pretty much all burden. I'm actually just trying to go through, having been through the ICD-9 to 10 conversion, and through three EHR conversions. It's all burden. Really, I don't derive much in the way of value from whatever coding set I'm using except for ease of billing, because that's largely what it's designed for. The day is coming, and I think one of the specific research questions from this is will this lead to better decision support? Will this lead to better probabilistic modeling of patient disease, condition, or of outcome? Will ICD-11 make some change in the support I get while I'm delivering care, that makes my job not only easier but what I'm delivering better?

Right now, I haven't -- other than billing coding, any change is just burden, and depending on which EHR I'm using, it's likely to be cost, too, because there's likely to be a version change or an update that has a financial cost that rolls to me. I don't mean to disparage this at all, but really that has to be one of the questions

is will that conversion lead to some value to me or to what I'm doing?

MR. LANDEN: I don't know if Bill wants to respond a little bit more directly to that, but I think big-picture-wise, one of the things we're addressing here is those are the type of questions we really did not ask or answer prior to our decisions to implement ICD-10. I know I've talked globally about that value proposition, and at a high level, yeah, you get a primary practitioner gets value back not directly, but very indirectly through the aggregated research, gets into the education and understanding, and so there is some sort of very indirect feedback, but the types of questions you're answering is, number one, how can we -- we know there's burden, no way around that. How do we minimize that? Then how do we ensure the types of value that you reference really get captured and get back to the practitioners?

DR. STEAD: In essence, that's why we elected to have a complete block on what are the perspectives and what are the key use cases from each perspective. That's a body of research that needs to be done to inform going beyond category 1. Category 2 actually can begin to be done in parallel, but 3 and 4 can't. Well, 4 can't; 3 may.

So that's where we would have to get that right, and whether we've said that well enough, that was the intent. That's where we've tried to capture it.

DR. PHILLIPS: I have been at this table as a guest many times over the past 20 years, and we actually did a whole project for AHRQ about if you had an instance like this where you were making a major change, what can you do for sector-specific need? For primary care, it's been an international classification for primary care that we've tried to say, can we implement this and create linkages so that the ICD-11 codes get generated off the back of that? It's the many-to-one issue for us.

It's that when you get granular, the ability to study things in a primary are setting goes down, because your buckets are too many, and our problems in trying to understand things, we need those coalesced, and ICD-11 doesn't look like help to me in that regard. What looks like help to me is we're at a transition point, could we do something different for different sectors, for cardiologists, for primary care physicians, for surgeons, that actually enables them to do better research or get better decision support, and generates the codes they need for ICD-11, so that they're meeting their needs and others' needs.

It's not just the value that comes back because of the coding system change, it's can I make a change for my setting that's important and valuable, and enables the change to happen? We've talked about this several times, the answer is yes, you can do that, but you can't if the intention's not there and it's not part of the research focus.

DR. STEAD: The other thing that has to play into that now is we only need to do in ICD-11 things that need to be done there. The things that we can capture in the appropriate -- promoting interoperability, if we ask these questions right, what we're trying to do is figure out what's the right alignment. What do you use each one for, and how do we answer those questions, and then how do evaluate fitness for those uses? Where we came out with, it's in essence an iterative process.

DR. PHILLIPS: I guess I'm just asking the research process, ask the question, too, what's missing? What's missing? What does this not do that needs to be captured or done? For us, it's typically reason for encounter, and the other thing that these coding don't do is allow capture of episodes. Is this a new episode, a recurring episode, or an ongoing episode, that lets you look at the epidemiology of your patient base, and how that leads back to decision support and predictive modeling.

DR. STEAD: I think we actually need to let Bob do that over the break. When you've got to look at where it would go -- whether we've actually got the right hook for it, because the bold here are actually the questions. The nonbold are the examples that sit within the questions.

MR. LANDEN: Just quickly, I'm looking at roman 4, number 2, might be a potential hook in there, where we're talking about fitness of ICD-11 to contribute to convergence of clinical, social, administrative information standards. But anyway, we will continue this conversation.

Promoting interoperability in interrelationships with other code sets and evaluating feasibility of computer assignment of ICD codes directly from EHR data, as contrasted to manual entry.

Number 6, evaluate feasibility of different timeframes for transitioning from morbidity. We threw out different years, 2025, 2027, 2030. Anywhere from essentially five years to ten years. Evaluate the carrots and the sticks, to hold stakeholders to an implementation timeline to avoid delays. Again, delays was something that happened several times in the ICD-9 to ICD-10 transition, and what experience there, that some of the organizations would prepare to meet the timelines, others would not. Therefore, those that did their due diligence and prepared

to meet the timeline wasted a lot of money and had to do it again, not once, but twice.

And then evaluating the lessons learned in pilots, evaluate the feasibility of repurposing and reusing ICD-11 for the same test beds, tools, databases, and techniques that were used recently in our conversion to ICD-10.

MS. GOSS: Denise, would this be an appropriate place to add a note regarding assessment of the interplay with state laws and regulations that might need to be changed?

MS. LOVE: It is not a make or break decision. If the country goes to ICD-11, states will have to change their laws and regulations, but I don't think that -- I'm not sure if it's in the equation anymore. Thank you.

MS. GOSS: I just want to make sure we addressed your comment.

MR. LANDEN: I'll ask you the same question again when we get to the communications plan, because that does talk about state legislatures.

DR. STEAD: My sense is we are good at this juncture with the research question, with the exceptions of whether Bob can figure out if and if so where we need to add a hook. I reread these. I think if we're going to do

it, it probably belongs in block 1. But we can come back to that after you have a change to look at it.

We'll take a 15-minute break. We need to start back right on time.

MR. LANDEN: Bill, before we do that, let me just check in with Frank and Jacki on the phone to make sure that they have an opportunity to raise any questions or comments.

MS. MONSON: No questions.

DR. PASQUALE: This is Frank. I think that the only -- I really like the presentation, I've appreciated the colloquy a lot, and I think that the only thing I would add is just that I do think that the question of the distribution of benefits and burdens is a really interesting one, and it might lead us to want to consult more with people in -- experts in reimbursement or others who might have a perspective on trying to ease that burden on clinicians or other people who are capturing the data, because I think there's a really interesting even business and economics debate about the value of data capture and trying to make sure that this isn't just added on to as another unpaid burden or unfunded mandate for physicians, and to get some perspectives from health economists or others about how do we avoid burnout among physicians who feel like they're just being utterly overburdened by this?

That will be I think a really important thing, and also the possibility of scribes. Is that something that we should investigate more? Can scribes do more to do this?

And then also, Eric Topol's Deep Medicine book, he described the capture of speech and translation of speech into text and other promises there. So I think between technological or paraprofessional adjuncts to physicians, or additional reimbursement to physicians and other clinicians and providers that are trying to keep track of this data, all of that should be part of the conversation. I don't think it's unavoidable that the burdens fall disproportionately on providers. I think we could create advice that would help avoid an excessive burden, and we should take on that task in this process.

MS. HINES: Two logistical notes. Thank you, Frank. We'll be going through this after the break and making any edits. I think what you've raised is captured here already, but let us know over the break by email if there's anything specific you'd like to propose be added to the outline.

Logistically, the rest rooms are down the hall. Go to the elevators, turn left. If you go down the elevator to floor G there is vending. You have to sort of walk through the lounge area to the second seating area.

There's water and juice and even some coffee. And Maya has an announcement about lunch possibilities.

MS. BERNSTEIN: We are told that because the cafeteria in this building where the lounge is closed some months ago, they bring in different vendors every day in the main hallway where you came in. Today there's Italian. I'm also willing to go to the Potbelly and get people boxed lunches for six bucks, a sandwich, a cookie, and chips. You can get drinks at the vending area.

I need at least six people who are staff and members of the committee -- sorry to other members of the public -- to do that. If you want to do that, I made menus, I'll go back to my office and get them. So you can just circle what you want, and we'll either get it delivered or I'll go pick it up. It's a block away. But we probably have to decide quickly.

DR. STEAD: Okay, let's take a break.

(Break.)

Agenda Item: Action on ICD-11

DR. STEAD: We have 35 minutes to get through the communication topic and the letter. So we're basically going to scan through the communications and hope that you've read it and are ready to ask us -- raise questions or concerns so we get to the letter.

Take it over, Rich.

MR. LANDEN: Okay, again, going as a recommendation to the Secretary, we'll cover the letter and the recommendation summarized, that HHS provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about to transition to ICD-11. The approach -- start now. Number two is critical and for our discussion today, it means that if utilizing a professionally developed marketing communication strategy means the professionals will take the guidance that we've got embedded here and will hone that. So I am less concerned about the recommendation detail in this letter because of the recommendation about using professional strategic marketing, and hence, we're going to be skimming rather than going into the detail.

HHS research findings become transparent as they become available.

Four, target each stakeholder audience. We have to speak to each audience in language that it understands and coming from sources that they trust.

Five, use multiple communications channels, and that's just a laundry list of what communications we think those market segments will identify with.

Roman two, essential messages to convey. ICD is coming and you have to start planning now. ICD-11 has some new, number two, ICD-11 has some new things in it. This is

not ICD-10 or ICD-9. So you need to think about it as something new, and not a continuation of the old. Three, explain why the conversion to 11 so soon, again, 2015 was our transition to ICD-10. Four, that we're doing the research that we need to determine costs and benefits. Five, we're doing the mappings that we need, and six, the clinical modification may not be needed, what that means to a community that's had a clinical modification forever.

Roman three, mortality-specific messaging. Messages to states, what changes they will have to plan for, messaging to researchers, messaging to policymakers, key audiences for morbidity, starting with patients and their organizations, professional associations, payers, vendors, developers, intermediaries. States, government, Medicaid, data agencies, policymakers at both state and federal level, standards organizations, coding professionals, quality software engineers, clinical content developers, and some of the implicit concepts in there go back to Bob's comments about how do we use this for the quality metrics and learning.

Oh I missed one. Somewhere in there is the point that Denise was bringing up -- five, yes -- state government to plan budget be able to secure any necessary legislative, that's it, I knew you were in there.

Okay, comments, questions? None at the table. Jacki, Frank?

(Noes.)

MR. LANDEN: Okay, ready to move to the letter. So the letter then takes the key concepts from the research agenda and the communications plan that we talked about and presents it in a concise way and is directed of course to Secretary Azar. Give some background description about ICD, World Health Organization, ICD-11, and then down at the bullets at the bottom if you could scroll up, please, Rebecca, talks about mortality and morbidity, clarifies the distinction between the two, and talks about mortality being a condition, nondiscretionary, whereas morbidity needs rulemaking under HIPAA.

Next paragraphs give some background information. ICD-10, mortality reporting began in 1999. Morbidity was 25 years after endorsement by the WHO. That was in 2015 that the United States adopted under HIPAA. References our letter of February 13 of this year, to the Secretary recommending updated criteria for adoption of health terminology and vocabulary standards and calling for adoption be supported by research confirming the benefits and estimates of cost including burden, burden of use, adoption, and implementation. Again, implicitly to some of the points that Bob was raising earlier. Talks about our

expert panel meeting, August of this year, and then names the research questions and the communication topics.

We talk about why ICD-11 is -- we consider to be a major advance over ICD-10. Again, biomedical and population health science, clinical practice, coordination with other classifications and terminologies, flexibility to reduce national clinical modifications, comparability of translations, support of online services to reduce the cost of implementation.

Next, we go into why we think research and evaluation of ICD-11 is important for the Secretary to initiate. The need for research we call compelling, given that ICD-11 may or may not provide significant opportunities, reduce burden, and increase interoperability, which are high priority areas for the United States.

We looked at the historical adoption processes and timelines and took them into account in formulating the recommendations. We acknowledge that adoption of 11 will be a years long process, but we need to start now to avoid a repeat of some of the quagmires that we had to wade through for ICD-10 adoption, and we're recommending HHS take a proactive approach.

Recommendation number one, that HHS conduct research to evaluate the impact of different approaches to

the transition and implementation of ICD-11 in the United States for mortality and morbidity classification. Talk about lessons learned from our previous transition, and looking for a better informed decision-making process with more information to stakeholders relative to more realistic estimates of cost benefits, public policy imperatives and opportunities. NCVHS has concluded that such research results would have facilitated rulemaking and smoothed the transition path for ICD-10 with significantly less controversy and burden.

Next paragraph talks about the currency of clinical knowledge. Clinical relevance, improved support for policy objectives. But evaluation of the potential -- we acknowledge potential, but we're also saying we need to evaluate that so we need further study to find the path forward that works for the country. Talk about the research questions in attachment B of this letter.

The committee calls on HHS to lead and support aspects of the research best handled by HHS and to engage experts from the healthcare industry and academia in other aspects of the research. Talking about an HHS industry collaboration, and referencing promoting interoperability, and it gives a list of bullets of topics to explore, so kind of a subset of the key areas that's contained in detail in the appendix.

We recommend that HHS -- if you agree, that means -- recommend that HHS complete the research in the next 12 to 18 months, because key questions regarding timely adoption and implementation will depend on the findings of the research. In other words, we don't know what a good timeline for adoption would be until we've got answers to some of the questions we're posing here.

Recommendation number two, that HHS provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about ICD-11 transition. That's what we went through with the communications plan. We stress then that every industry stakeholder was somehow or another affected by the changes of the versioning, from solo practitioners to largest industry payers, state and federal agencies, private sector technology companies. So everybody.

We point out that largescale change requires effective communication and that we need a trusted source of truth for the industry, and that might have served us better from ICD-10. Certainly that's not an omission we want to reoccur with the transition to ICD-11. People need to hear the message, and they have to hear it from people that they have some belief in, some respect for, and to get that we need the evidence, and we need to start early.

Subject matter experts that this committee heard from have urged us to recommend that HHS take the lead in ensuring there is early and targeted communications about ICD-11, including status updates on planning and research. And we reference the detail of attachment C to the communications plan. Again, the list of some of the key areas in the attachment. Like the research targeting a timeframe over the next 12 to 18 months.

Recommendation number three, which we have not discussed in this morning, but did come out clearly in our expert panel and from other discussions is that there are currently unresolved copyright issues between the World Health Organization and countries who use the ICD, who will be using ICD-11, and this recommendation just raises that issue for the Secretary's attention, and asks that the Secretary give appropriate level of priority and support for the -- so that there will be a resolution to the copyright issues worked out between the United States and the World Health Organization by whatever time we implement ICD-11 for mortality and morbidity, and the National Center for Health Statistics is the liaison who will be handling these negotiations with WHO.

All right, so we wrap up with committee's assessment that taking a proactive approach to research communications and copyright for the transition will enable

the United States to identify the optimal path forward, maximizing benefit and minimizing cost. Then thanking the Secretary, and that's the letter.

So, members of the committee, are there issues you'd like to flag? Anything we've omitted or something there that you are not comfortable with? Jacki, Frank, on the phone?

(Noes.)

MR. LANDEN: All right, you've been given an opportunity to kick the tires, and I think the -- from the body language around the table that it speaks volumes to the quality of the work that the expert panel, staff, committee members, subcommittee members have put into this.

So Mr. Chairman, I suppose I should hand it back to you for a motion?

DR. STEAD: Thanks, Rich, and thanks to the standards subcommittee.

Want to loop back to Bob's question, because we need to try to put that to bed, because the attachments are an integral part of the letter and therefore approving the letter is approving the attachments. And so we have to see if you've had time to examine the situation and come to a thought.

So can you talk us through them -- do you want us to pull up the research questions? If you can pull up the

research questions and zoom so we can deal with it in real time, if we're all comfortable.

DR. PHILLIPS: Probably the most impactful piece is under that section one, as you suggested, Bill. Number three. So I had two questions there. The first is what benefit or benefits would each sector find compelling for change?

The second, and this is for the healthcare sector, is what do EHR vendors estimate the cost of conversion to be for them and for customers? And I realize that introduces the opportunity for someone who doesn't want something to happen to put a large price tag on it, but I think you need a realistic estimate of what the cost will be. What do the EHR vendors estimate the cost of conversion to be, for them and for customers?

DR. STEAD: From a formatting point of view, those would be nonbolded examples under the base question. Just being clear.

DR. PHILLIPS: Do you want me to do the next one or do you want to discuss these first?

DR. STEAD: Let's find out whether any -- whether everybody's comfortable with those or whether somebody has questions about whether that additional detail is helpful.

MR. COUSSOULE: I think the detail is helpful. I think it's also very consistent with the letter

recommendation that talks about doing an appropriate amount of research to find out where the issues, burdens, challenges are. So I would support that.

MR. LANDEN: I would suggest expanding beyond EHR vendors to software developers in general. So EHR and software developers, instead of --

MS. GOSS: There's going to be a huge impact not just to the EHR vendor, that needs to be its own thing, plus software developers. So it's EHR vendors and software developers. The distinction getting at, Rebecca, is it's one thing to have an EHR product on your desktop that you're using, there are ancillary software programs that you use to help in care delivery, and all of those are going to need to be modified as well.

MS. LOVE: I concur, because it's analytic vendors, software tools, it's just the full gamut.

DR. PHILLIPS: You may know this best, but with so many quality measures dependent on codes for the numerator and denominator, it also has potential impact on the quality measurement community. I didn't put that in here because I hadn't thought of it until we were having conversations over coffee.

DR. STEAD: And I think our challenge is what's the right level of insert that doesn't make us have to

capitulate the whole ecosystem, and from my thinking, are you really talking about system integrators?

MS. GOSS: No, I'm talking about actual -- Nick started this, but I'm going to add on to it. I think that it's about the products and tools that are wraparound enablers to the EHR functionality that lets, that supports the clinicians in care delivery and other obligations they have in their practices.

DR. STEAD: So I may be showing my own heritage -- I think of a software developer as someone who develops software.

(Laughter.)

Not as a type of company.

MS. GOSS: Okay, so software companies, EHR vendors and software companies.

(Cross-talk.)

DR. STEAD: We are trying to get a broad concept here, and we somehow have to get the broad word.

MR. LANDEN: It might be helpful to say EHR and other healthcare software companies. Or healthcare software products. Possibly health information technology developers.

MS. HINES: So EHR and health information technology developers.

DR. STEAD: Vendors. You're really talking vendors.

MS. HINES: What do you want to do with this? Does that work? Okay.

DR. STEAD: So are we good with that change as reworded? Okay.

DR. PHILLIPS: The other one was under 2. It's number 1.2. Under A, I've added this second double I, and this one's a little bit -- this starts to get into weeds but it's an important issue for me. Is the change to ICD-11 an opportunity to introduce -- and I'll reread this, Rebecca -- other sector-specific changes, i.e. ICPC for primary care, to better support the sector while enabling ICD-11 adoption or outputs? ICPC, that's the International Classification for Primary Care.

MS. HINES: So it reads is the change to ICD-11 an opportunity to introduce other sector specific changes i.e., ICPC, which we'll spell out, to better support the sector while enabling ICD-11 adoption or outputs?

MS. LOVE: Is it the ICPC changes that need adoption or the system or the classification?

DR. PHILLIPS: ICPC is a WHO recognized classification scheme that's used in several countries. It enables outputs of ICD-10 currently. It's being retrofitted to put out ICD-11 so it allows those outputs,

but it allows the sectors' particular needs around classification to be used up front. So if you're going to make a change, why not make a change to one that actually benefits the sector but enables the other? It's a bigger kettle of fish, I understand, but it's the value proposition.

MS. GOSS: Bob, I am not quite following -- other sector specific changes. I'm not getting it.

MS. HINES: So he's focused specifically on his, so I think you're talking, Bob, about --

DR. STEAD: He's talking about the primary care sector within the healthcare delivery.

DR. PHILLIPS: I was about primary care versus subspecialty care, and I'm adding that there are other sectors, other changes that any of them would find valuable that would enable ICD-11 and not compete with it. If we're going to make a change, let's make a change.

MR. LANDEN: Technical nit, the i.e. should be an e.g.

DR. STEAD: I simply have to admit my ignorance in that I do not know the degree to which this question has been resolved within the structure of the ICD-11 foundation, et cetera. So, we're in a tricky problem in that we're really getting a technical recommendation now, when we don't have the technical experts at the table. So

I guess in the interest of trying to move this forward, because I know what you're trying to do and -- I guess I would suggest we see if we can get a motion to approve the letter with the attachments, subject to our discussing the wording of this addition with the experts that have helped us in the past, people like Keith Campbell and Olivier, Jim Cimino and others, to make sure that we're wording this in a way that achieves your purpose. But I think we need the chance to loop back and I'm not sure we can do that in real time. I'd rather go on and get the approval if we can and figure out the right process to do that loop back.

DR. CORNELIUS: So, I'm wrapping my mind around the process. Is that we vote for everything but this, and then we create a means to amend our vote or what? I just want to make sure we're clear for the record, what we're doing.

MS. HINES: What I hear Bill saying is the experts who provided so much input into this outline would need to be consulted to make sure this makes sense.

DR. STEAD: The wording, right, how we may have to loop back to Bob -- we've got the intent right, but with wording that makes sense --

MS. HINES: Right, so the intent is the same, but make sure the wording is actually sensible from a technical standpoint.

DR. PHILLIPS: I'm happy to participate. Do you need a motion to pass this -- to get it back to them for that input?

DR. STEAD: I think that Lee is helping us be -- process-wise, we need a motion to approve it without the sub-bullet. And then we need a second amendment to add the sub-bullet after we get the right language from experts.

MS. GOSS: I would like to make a motion to approve this body of work with the ability for the experts to be consulted on this particular item to 2, I think it's 1.2.A.2, and that if any further modifications are made that it be vetted with the executive committee.

DR. CORNELIUS: Second.

DR. STEAD: Any discussion?

DR. PHILLIPS: My only discussion is I should have led with this; I'm very grateful to the group for producing this. This is incredible work and very important. So thank you. And I also want to respect the fact that this is embedded in a research set of questions. It's not a directive. It is a part of the research endeavor, so it is not -- it could lead to a directive, but it is part of the research effort.

DR. STEAD: I'm hearing silence from Frank and Jacki. Are you good, Jacki?

DR. PASQUALE: Sounds good to me. It's great.

MS. MONSON: Yup, I'm good, too.

MS. GOSS: So I want to echo your sentiments. This has been a tremendous amount of work, and we could not have gotten it done without the support of NLM, the VA, NCHS leadership. It's enabled us to also continue on my favorite topic of predictability roadmap, so I thank you, Bill, for enabling us to have parallel streams. Your leadership and support has been instrumental in the standards subcommittee being able to accomplish as much as they have in the last year.

On a less positive or happy note, it was very sad to see that one of our staff support who was also engaged in this, Mike Lincoln, suddenly passed away, and I just thought it would be appropriate to put on the record our appreciation of his support of the full committee, the standards subcommittee. His passing is a loss for all of us.

DR. STEAD: Thank you, Alix. Very appropriate additions, thank you very much.

Since we're ready for a vote. All in favor?

(Ayes.)

DR. STEAD: Any opposed?

(No response.)

DR. STEAD: Congratulations.

Okay, do you want to do the honors of introducing --

MS. GOSS: I do want to do the honors of introducing Ms. Cathy Sheppard. All right, so this is a -- as many people know, I spent my tour of duties at X12, garnering my standards badge of honor, and so it's very much a pleasure to introduce Cathy. She and I worked together extensively at X12. We didn't always see eye to eye, but through those debates and arguments we created great solutions together.

She's volunteered for 22 years within the X12 community. She knows the ins and outs of that, which made it a natural progression for her to become the executive director four years ago. X12 is lucky to have her. She's bringing innovative thinking, a sense of history to try to chart the successful path forward for X12, and having the opportunity to present at WEDI last year on our predictability roadmap efforts, I had the opportunity at that meeting to sit down with Cathy and learn a lot about the progress that they've been making as an organization in incorporating the lessons learned and the feedback from their various efforts in the healthcare industry, but also recognizing that X12 is a multisector standards body, and so what I thought was appropriate was for Cathy to come give an update to us, and to the industry as a whole on

where X12 is at and where they're headed. She has a very extensive presentation to deliver to you today, to paint the full picture of X12's current status.

So what I would like to do is turn the presentation over to Cathy and ask that we hold our questions so that you also get the benefit of the full picture, and then we'll have time for a Q&A when she's gone through all of her slides.

So, thank you, Cathy.

Agenda Item: X12 Update and Enhanced Implementation Guide Processes

MS. SHEPPARD: Thank you, Alix. I don't remember any arguments. I only remember a loud exchange of ideas, that sometimes resulted in -- nobody ever argues with anybody.

(Laughter.)

I thank you for your invitation to be here today. This obviously is very exciting information. I do plan to move through it quickly, but I'm happy to have individual conversations or come back at a later time if we need more details.

Trivia. We don't have a large number of topics today, so this is just a quick synopsis. We'll just move on to the next slide.

I wanted to start at the beginning for some of you, because I find when I'm talking to people lately that there are more people who don't actually understand the details of the X12 organization than do, even though most people think they do. So we have a handful of staff, a very small handful of staff. Hundreds of members, and more than a thousand representatives of those members that come to the table to work with us. We have corporations, associations, organizations, people classify themselves all different ways. We have an accommodation for all of them, including individuals as members, recognized members. And as Alix said, we cross the sectors, so we include healthcare, insurance, transportation, finance, government, supply chain, and some subindustries that work within those big broad industry sweeps. So we have a lot of irons in the fire at all times.

We are accredited by ANSI as a consensus-based nonprofit, and we have a charge from them on our area of responsibility, including the development, implementation, and ongoing use of electronic data interchange standards which happens to be of great interest to this group and the group that you are representing.

What do we want to do? It's a lot -- formal mission statements and vision statements can sometimes be formal, so we put together these guiding principles. We

want to have stable and trusted products that support data exchange. We want to be open minded with vision and insight ourselves, and we want to listen to those partners that we have. We want to collaborate with them, and we want to have a financial model that allows the organization to continue to do this work for the long term.

What many people don't understand is that X12 standards are the workhouse across the industries in the United States already. Retail, supply chain, transportation -- all of those are powered by X12 transaction sets. Including healthcare in that list gives a broad spectrum of pretty much every organization in this country is using one or more of our standards. We have billions of those transactions that get utilized across those industries, and internationally as well, and millions of entities have implemented them. It's not a small base. And those companies that have implemented have a strong and stable infrastructure that meets their needs seamlessly at this point, for the most part.

What we're finding more and more as we reach out and survey and do outreach is that a large percentage of people who are gaining value from the X12 standards don't know they're using them because they're so complexly involved in their normal processes that they don't recognize that X12 is the transaction set that's powering

the work that they're doing. We think that's a great testament to how stable and trusted the transactions are. Because if they were causing issues or not working well for the intents, they would of course be much more visible to the people that are benefiting from them.

Most of the people who are exchanging X12 transactions are using the EDI standard, and many people just call that X12. Are you sending that in X12? But it's important to realize that we have other syntaxes besides the transactions, loops, elements that you're all familiar with, and those are available and being used in other industries more prominently, but they're also available for healthcare, and we have some number of people that have implemented using our XML version, for example.

The data that we're exchanging has been use tested in production for many years, and it's well defined with relationships and definitions, clearly known to sender and receiver.

So, these are just observations that won't come as a surprise to any of you, right, that 20 years since the X12 transactions were first mandated, lots and lots of things have changed, but some things have remained the same because they're working, because they're good. The healthcare industry continues to evolve. That means new requirements, and it also means changes to requirements

that used to be in place that aren't relevant anymore. Technology emerges, and many of those emerging technologies can support or otherwise expand the technology that's already in place.

The ASDs, those are the ANSI Accredited Standards Developers, and other standards or development organizations continue to change to respond to needs, and continue to work together to ensure that our changes are in line with each other, let's say that. All of us search for balance among the needs of the stakeholders, and that's one of the things that you guys focus on very well here, and that the people that sit in the back of the room for all these meetings gain a lot of value from listening to those conversations. We're talking about the primary care physicians, we're talking about the consumers, or we're talking about the hospitals. We've talked about all the stakeholders in this environment frequently.

We also want to put forward that you know we've been doing this 40 years. I'm not going to say that Margaret's older than me, but between us we've got a lot of years of developing standards and we understand the data. We understand the environments, the stakeholders, and sometimes we understand the pitfalls more deeply and with greater scars than some of the other people who were privileged to start a little later in the process.

That leaves us in a great position to help the whole industry as they move forward, because we've learned a lot of lessons and there's no reason for new SDOs or for this body to learn those lessons as painfully as they've been learned in the past. So we're happy to be invited to be part of the solution, to share those lessons for the good of moving forward. We will continue to support our install base as a primary function. As you heard, there are millions of organizations depending on us doing that, but we do not think that that is contrary to also expanding to meet new needs and emerging needs and we can do that by focusing on key initiatives, which I'm going to talk about in a minute.

The important things to remember also is that our syntax is scalable. You want to send five transaction sets, that's great. You want to send 500,000 a day, that's great too. We can support both of those very small and very large transmissions. When we get it right across different verticals within our industry, we improve efficiency, reduce cost, and expand reach of organizations without incurring additional effort on their side. And like I said, we want to share what we've learned. We don't think that that learning curve has to go to waste, and we're happy to do that.

Most people in here are familiar with the X12 EDI standard and technical report type 3s. We have other work products, and we've listed a few here just to keep in the front of your head. We have implementation tools that help implementers who want to implement one of the standards, and we have actually three additional types of technical reports besides the implementation guides that you guys are familiar with. All of those things work together in tandem. Some of them are very detailed and some of them are very much all encompassing.

The EDI standard and the metadata that allows that standard to exist is really made to be all things to all people, which is great in many regards, but it doesn't help when you have a specific use case or a specific problem you want to solve. So the technical reports and schema and some of the other items are more use case based, and our use cases might not be as small as some use cases that we're used to talking in the industry today, like the use case may be all purchase orders.

I'm going to try to use examples today that aren't about healthcare because that will keep us from getting sucked down into side discussions of that, but the use case for purchase order is not definitive to a purchase order for goods, or a purchase order for groceries. It's

just about a purchase order. We also have more detailed use cases, which come out in implementation guides.

We understand that there's sometimes not a clear knowledge of how many collaborations and initiatives and cooperative works we have in process. I know that you will not know all of these acronyms, and if you do, I would like to buy you a soda after lunch. If you have a question -- Pilotfish, they give really, really fun toys so we like partnering with them. I'm happy to talk about any of these collaborations with you at the break or at lunch, I'll be here tomorrow, too, but for this purpose it's just to show you that we are open to collaborating with almost anybody who has an interest that aligns with ours, and we do that very frequently and successfully.

Some of these initiatives you will be more interested in. They're much more pertinent to what you're doing, so I called them out. We're working with Da Vinci currently on a crosswalking project that is actually turning into more than crosswalking. We started with the idea that we wanted to make sure that data which has different names across different systems is clearly used interoperably the same way, and the way to do that was going to be to mount the names that are used on each side.

We thought that would be a simple step. What we're finding is that there's some data that the Da Vinci

site believes is perhaps no longer relevant to the crosswalks that are being created. So we're having additional discussions. We're going to vet their findings with our own implementers, and we will either return to them some enhanced message from stakeholders that they haven't been able to consult with as they're going, or we will find evidence from our side that supports their position that some of that functionality is not necessary any longer. So what started as a simple collaboration of let's map these has become let's make sure we have these requirements right across organizations and for the industry. So it's exciting when something morphs into added value in the middle.

We often have initiatives in place with NCPDP. At the current moment we're working on implementation guides with them that will explain the use of the X12 transactions for retail pharmacy, retail specialty pharmacy -- not retail, specialty pharmacy functions. They don't need to reinvent the wheel. We already have the wheel, they just need to give the instructions, and we're happy to help with that. So those implementation guides will be coming out in 2020.

We also have a number of initiatives ongoing with CORE, and we seem to add more to the CORE X12 activity list on a regular basis. We're trying to work on ways that we

can integrate the instructions that CORE provides in their operating rules, and the related instructions that are in our technical reports and our implementation guides so that implementers only have to look one place to get the information that they need. That is a direct result of many discussions here in this as part of the roadmap, and before the roadmap, that it's too hard for people to find things if they're scattered across organizations. We're trying to centralize that information.

We're also working on increasing feedback both sides by utilizing the base on each side. So when we need to gather feedback, we're going to use the CORE resources for that when we need to gather feedback about implementation, they're going to use our resources for that. And we've recently started a new series of joint webinars, and those webinars are planned from now well into 2021, as an ongoing training and information set.

We have other initiatives that are less directly related, but that I thought you would find interesting. We started working with an industry group that is very, very focused on using X12's vast vocabulary and our data type system to integrate more quickly with other technologies, and they have recently requested and been granted a new position as one of our subcommittees. So this business to everything industry group has become an X12 subcommittee,

and they'll be focusing at the beginning of their work on supply chain. That is where this started, and then hopefully the other industries can build on that, on the lessons that they learned. In this country, we have followed supply chain and retail and transportation through EDI since the beginning.

We're also working with the Blockchain Alliance to use our data to speed their blockchain functions. They want to get those blockchains up and running quickly. We've had a lot of discussions about the fact that building on our metadata will save them years of development time to do that. And we're working with PEPPOL which is a European e-procurement effort to try to bring some of their processes into the United States.

So you heard me talk about the B2X group, and I think all of you are familiar with the left side of that box. The ASC Committee, that's our committee that develops accredited standards, the ones that meet the ANSI criteria. That's fairly rigorous. The RSC or the Registered Standards Committee is a relatively new committee in X12, and it focuses on X12 products that don't require the rigor of ANSI. So if we have something that for example in blockchain that needs to move forward quickly and doesn't have to follow ANSI's consensus-level verification process, we can do that under the Registered Standards Committee and

move that work forward very quickly to meet the needs of those subgroups. The RSC is still a consensus-based process, and the speed comes because there is substantive agreement among all the stakeholders that doesn't require a lot of debate or discussion, not because we've removed the consensus. So these are highly agreeable activities.

MR. COUSSOULE: I'm sorry, can I just ask one question -- how do you decide? Or I could wait to ask this --

(Laughter.)

MS. SHEPPARD: I will try to remember that question, Nick, and you can, but the quick answer is that the groups usually know which side they want to work under. Because if you want the power of the ANSI accreditation behind what you're doing, then it's not a decision. So the groups that don't need that ANSI stamp of approval are the ones who may choose to work under the RSC. Okay, we can come back to this slide during questions.

We have heard not just here, but often here, that it doesn't seem like we're listening, so we're trying to work on the perception. We think we've been listening, but if other people don't think we've been listening, then we need to listen better. So we've started that by getting our members and some of the public used to answering our questions when we have outreach by setting up surveys. The

beginning surveys have been simple and easily responded to, because we want people to think when they see this note from us asking us to participate in a survey it's not going to be onerous. We've had surveys on things like where should we have our meetings? Should the meeting logistics change?

We've also started to become more in depth in those surveys. Do you understand how to get a license for our IP? Do you create companion guides, and if you do, are you basing them on our IP use policies, and also about how people would like to consume the standards. Have you created a proprietary schema based on X12 efforts? Did you know that X12 has schema that are available for use? So we're trying to get these surveys.

You can see the surveys, the past ones, and their results, and you can see the current survey at any time by going to this URL, which is also accessible on our homepage. So if you want to see what the survey results have been on any of those things, that's out there for anyone to see. We also added a permanent online form called feedback form, and we help categorize things by adding a drop-down list that says do you want to talk about these 10 hot items, but we also take feedback about any topic that anyone wants to provide at any time on that form. And since it's a permanent form which we haven't had

in the past, everybody's beginning to learn where it is and use it more often.

So we're also listening to the -- this is hard. We don't want it to be hard, we've never wanted it to be hard, so we're doing some things to make it easier. We rolled out our online viewer this year. It's the first time we've had one, we were excited about it. It is being very, very well received. So, in the online viewer you will find all of X12's published products as we get to them. They're not all in there today, but they will all be in there, and the list of things is growing weekly. The guidance documents and the underlying things that explain how the standard is developed are included. The technical reports are there, and all versions of the standard.

So if you have access to GLASS, then you have access to X12's full body of work, or you will when it's fully populated. Glass is a separate license, and X12 members have two licenses, so that all of the X12 members, primary and alternate reps, can dig in and get busy, working in that online tool and they're finding it very powerful. We also have individual licenses for people. Just so we're all clear, though, this is very -- it's not onerous at all. It's less than $200, around $180 a year to have access to all of X12's products.

And people have begun asking us for enterprise licenses, because they want to give a license to 1,000 of their employees, and so we're working on those, and we're developing another path for those people who want to license a large number of people at once.

I know you can all read this and see it in great detail, so the point of this slide is to show you that what you see in Glass is what you're used to seeing. If you're used to using the standard itself or if you're used to using a technical report, you're going to see something that looks very familiar. There's not much learning curve. The learning curve is how to use the menu on the left side, and that's about it.

We also heard in this body quite loudly a couple of years ago that it was confusing for the industry to -- for us to change the name, being the number, the reference number, every time we have a new version. So we went back to the drawing board on that and, moving forward, you're going to see that we've adopted a new naming standard which says beginning with 7030 across all our industries, not just healthcare, if you have an implementation guide, that identifier number will stay the same going forward. The only thing that will change is the version number in the front.

So the 5010 version of the health claim payment advice was 5010X221, 7030 it's X322, and it will be X322 for the rest of its lifecycle. So we're hoping that that will reduce the confusion over which guides replace which guides, and make it a lot easier for us to talk long term about a piece of work as it evolves.

We also have heard very clearly that examples and test data are of extreme interest and they're causing a lot of pain points to our implementers. So we've created an example library and we started standing it up with our own examples, and we offered the ability for other people to contribute examples, which they've done. But we could quickly see that wasn't enough to meet the appetite for examples, and it doesn't give us the beginning of a test bed that we can use going forward.

So we recently began partnering with GenRocket, and they are working with us to create a robust example library that will give across our industries real-world test data for specific examples. And this is the first step in a process that will get us to a testing and certification to help with that issue we hear about frequently, that it's too difficult to get a test bed to test the X12 transactions.

We also heard that maintenance requests coming in from 37 different ways and 26 different forms was too

confusing. Our first step, all of our maintenance requests are now at one site on our form, and the conversion into a single maintenance request form has started. So this process is going to keep getting simpler and simpler as we move forward. So now there is one place to go on the X12 site to put in your requests, no matter what those requests are about. And that even includes if somebody wants to request a change to a policy or a process. This is all inclusive. You want to change anything that comes under the X12 umbrella, this is where you do it. Hopefully that will help with people who say they don't know where to go when they need something.

On that same note, we have listened not just here, but here and many other places, and we know that we need to have continual improvement in our processes, which we do. So right now and for most of last year, X12 has been working on simplifying our maintenance process, while still remaining compliant with all of the ANSI requirements for their accreditation. And our goals have been to support a predictable and reliable schedule; those words should sound familiar to this body.

We want to solicit more public feedback earlier in the process; again, a common theme that comes across in these discussions is that it's too late by the time people feel like they have an opportunity to weigh in. We want to

streamline the processes to make them not only quicker, but also simpler and easier to understand, and we want to reduce the burden on our member representatives, because I think everyone in this room knows those people are doing a huge task today. So those were the goals that we started from.

As background, we currently have two maintenance processes. One has been stable and solid for many years, and that's the process we use to maintain the standard and the metadata that builds the standard. That data has been called our DM process, it's been called a maintenance process, it's been called a change process, but through time it's been the same activity. We have a not-so-predictable process for publishing our technical reports, and again that's not just our implementation guides, that's all the technical reports that we produce.

So going forward we're going to integrate those into one process that's built off of the established and predictable cycle process, and the end result of what we're doing now will be that we publish all of our work products once a year, with all revisions that have been completed since the last publication cycle, and people will have them available. You can use them, you can talk about them, debate them, name them, you can move them forward or not, but they will be there and they will be there at a set time

all the time. Hence dependable. Predictable, that's the word.

Again, I know you can all study this and see all the steps that go, but I want to keep this at a really high level just to show you that there are still a lot of steps because there needs to be a lot of steps to get input from the right number of people to ensure the technical accuracy and to make sure that ANSI requirements are met, but this is a more simple flow through those processes, and just one way. So we're still going to have vetting.

What I would like to call particular attention to is the third box which says public input solicited. So that's a new step that we're going to put in place. That is the very first thing that happens when a request is received. Before we start working on it, before we have a predisposed leaning towards how we want to answer it, we're going to go out to the industries -- again, not just healthcare but all of them -- and say, industry, what do you think about this request that we received?

That input is going to need to be simple, right? I support this request, I don't support this request, I might support this request if you changed it. So we're going to try that. We're going to give it a try for a while, a couple of years probably at least. Then we're going to evaluate about whether people really are engaging

earlier, if they have the opportunity. If not, we'll try another way to make sure that we're getting input into our work.

We don't have time to do hours and hours and hours of work that the industry doesn't want, any more than the industry wants us to be spending our time doing that. So that public input is directly a result from the comments that have been made during the roadmap process that say it's too late in our process when we collect information.

You also see at the end, three up from the member ballot step is the annual public feedback cycle, and that's a place -- that is not a place to request changes to the documents, but that's a place to review them and give general feedback on this is meeting our needs, this isn't meeting our needs.

So those technical reports that are going to come out every year are going to come out in our technical report library. You can see it's going to be in our Glass tool, but going to be easy to grab those reports in the year that they're published and access them that way. This will be a good reference for anybody who's looking to see what's available but isn't yet put into play. So the technical report library is a new term you're going to be hearing more of, and we wanted to make sure that you understand what it consists of. The top part of the left

bar are the implementation guides that were published before the technical library was created. So the 5010s and those legacy reports will stay in that section until they're no longer relevant.

So we know that all of this comes down to the question of metadata and syntax, and we know that standardized syntax is not enough. We have to have consistent data. It's called different things as we go. It's interoperable data, it's transportable data, it's shareable data. The efficiencies that we need to come, come from the standardized data far more than they come from the standardized syntax. If we can standardize that data, then it doesn't matter how you consume it. Everybody's going to be able to their trading partners in the way that their trading partners need to talk to them. Those definitions that we have in our metadata, the ones that we were talking about earlier, they've been use tested and in production, and they're available in many ways. The problem is that we don't always let people know how that is available.

So our metadata repository that sits under the EDI standard that you all know, it describes the data, it describes the relationships to the data, but it describes it without syntax. And all of our work products are based on this layer of metadata that we've not made visible to

people for quite a long time when we should've been. We'll say, we have not been good at promoting what we have. We haven't been good at letting people understand the power that exists there. So we're going to address that.

So, if you go down to the metadata level, and again, I picked a non-healthcare example, because I don't want us to get sucked into the weeds. Proof of delivery is a simple concept, and you can consume proof of deliveries and create them in many syntaxes, but at the end of the day, you need to be able to tell someone the date, the time, and who received the delivery. That's the level of metadata that sits underneath the EDI standard underneath our implementation guides, underneath our XML.

So we want to start exposing this to people. So we are also unveiling a new product that will show the metadata itself, and that metadata will be shown in syntax-neutral form, and you can choose while you're looking at the metadata to see it in a syntax-specific form. You can look at the base relationships, or you can say I'd like to this in the EDI syntax, I'd like to see this in JSON, I'd like to see this in XML, I'd like to see this in FHIR; however you would like to see that, you'll be able to draw those correlations quickly and easily to understand the different ways you can send and receive this common data that's well described.

The fact that we haven't made our underlying data visible has helped I guess perpetuate the myth that you can't do APIs based on X12's syntax, which you can. We hope that the bridge will allow people to see and understand how to build those links and how to use the base data and the structure that is defined there to build the APIs that they need to do their individual work. But this allows the people, the implementers that already have invested in the EDI standard and have the syntax available, to know how to use those relationships just like the crosswalking between Da Vinci and X12.

The crosswalking will allow people to build APIs against that data, and this isn't new. It's only new to healthcare. We have in the other verticals that X12 supports, they've been doing APIs based on our EDI transaction standard and our XML for an extended period of time. We do understand that we can make this easier. We're going to work on that, and we're going to make sure that we are better at sharing the message so that people understand the options that are available.

So the way we think we can do some of this is that we will pair things together in new ways to help people leverage the technology investments they've already made. We'll use the foundation that's already there to expand things, and I think the most important bullet

probably is the third bullet on this screen, and that is, if we want interoperability and we want smooth data transitions, we have to work together sooner and better. We can't have smooth interoperability or support multiple syntaxes until we do a better job of communicating, until we cooperatively identify alternatives and the pros and cons for them, and until we have all the viewpoints considered much earlier in the process. The much earlier in the process point needs to be made across the whole healthcare industry and this body is well positioned to help make sure that those conversations happen with all parties sooner as we move forward with new -- the technologies that we're considering emerging now aren't going to be emerging long. They're going to be has-beens soon, and as we approach new, we need to talk about those things sooner and better and we hope to be at the table here for those discussions.

Just to wrap it up, we've changed, we're going to keep changing, but we're also going to stay the same. We're not going to abandon our implementers, we're not going to abandon our strengths, and we're not going to lose focus on what we do well, while we expand into doing more things that support the needs that are being presented to us. We hope that as people find new things that they want to do, that they come to us in our simplified processes,

and we can start moving them forward at a much more rapid clip than we've moved them forward in the past.

Here we go. Now I'm ready. How did I do?

MS. GOSS: Thank you. You've provided us with certainly enough time for questions and answers.

Nick, do you want to kick us off? Do you have any other questions -- I know I have like seven I've taken.

MR. COUSSOULE: Different question -- you mentioned an annual update cycle. How do you spread that through the year, and what's the thinking process around that, or is it kind of like flip a switch on April 1 and off we go?

MS. SHEPPARD: So X12 has a process that allows for maintenance request solutions to be balloted three times a year, but the output from those ballots is published once a year. So, we will do our work as we've always done through the year, and three times a year we'll have a ballot, and the work revisions or new work that is approved during those three ballots will manifest once a year in an update. We're really excited about this because another thing that you hear about frequently is our difficulty with change logs, and technical change logs versus functional change logs, both of them are going to become automated in this process. So not only will we be able to tell you here's the new version, but we'll be able

to give you, for those who would like to know, every single bit or byte that changed. For those who just want to know what functionality changes, we'll be able to produce that too.

MR. COUSSOULE: So will that once a year be the same day for all the standards, all transactions?

MS. SHEPPARD: It is not always the same day, but it will be the same for all of it. Sometimes we get it out at the beginning of January, sometimes we get it out on January 15, but when it comes out, it will be everything. We reserve the right to split that later into partial, like the standard in January and the implementation guides in February, but the plan is we're trying to get it all out at once.

MS. GOSS: So Frank or Jacki, do either of you have any questions since I can't see your tent cards?

(No response.)

MS. STRICKLAND: So I understand that you are going to release the transactions, assuming on a predictable schedule. How are you going to make up the difference between where we are today versus whatever you kick off for the next version, because we've been waiting for a very long time and there's a lot of changes in there, but there's also a lot of changes in there that the industry doesn't even need anymore.

MS. SHEPPARD: This new process will start after implementation guides that are in process now are completed. So the 7030 work that's already in process, we'll complete, and when there's a natural break, then they'll start using the new process. So for the next year, year and a half maybe, we will have to keep maintaining two processes, because we need the 7030 work that's in process now to finish its cycle so we have a clean start for the new unified process.

MS. STRICKLAND: So you're assuming that 7030 would come forward, get adopted by HIPAA, everyone would do all of those changes?

MS. SHEPPARD: Well, I'd like to keep that separate if we could. We're assuming that 7030 will get published as it's being developed right now. That's a true statement. What we bring forward as a recommendation to move to the next version isn't finalized. So I don't want -- I'm not saying we're going to implement 7030 and move forward. What I'm saying is on our side we're going to finish 7030, and then we're going to start this new process.

MS. STRICKLAND: With what base, 5010 or 7030? And as you do this predictable cadence, you will be doing it as a suite?

MS. SHEPPARD: 7030. Again, the suite concept is only about what has moved forward for adoption under federal regulation. So we could talk about that separately. What we're going to move forward I guess technically would be a suite, because once a year we're going to publish everything, and that's a suite. The intention on X12's side is that going forward there's not likely to be a suite ever again. We're going to present things that are needed by the industry that new functionality or enhanced functionality or as you heard me say for the 278 skinnied down functionality, whichever it is will be moved forward based on need, based on what the industry needs to accomplish its goals.

MS. GOSS: Let me just chime in here, because I'm looking at some blank faces around the table. So let me clarify when we're talking about the suite that Deb's referring to -- we have in seven medical-related IGs adopted under HIPAA, and those that were adopted under HIPAA are considered a suite that you start with the enrollment premium payment, you go all the way through the claim, so that bundle is what Deb is using shorthand to refer to as the suite. And great deliberations and debates have occurred over time about whether you have to advance all of the transactions and their corresponding

implementation guides as a suite, and what does that mean to industry adoption.

So this is something important for the full committee to kind of stick away in the back of your brain is that we anticipate based on Cathy's comment that something will come forward through the DSMO process to NCVHS for consideration as the upgrade to 5010. That may or may not be a full suite, meaning the soup to nuts of the original HIPAA-mandated transaction implementation guides. So stay tuned.

MS. SHEPPARD: I would like to come up with an example that wouldn't make some people's head explode, but all the examples I can think of will cause other aches. We could use Rich's, when ICD-11 is something that needs to move forward, it may not touch all of the transactions that are mandated. So there wouldn't be a need to bring things forward if we were satisfying that request, only if that was the only request that needed to be satisfied.

MS. STRICKLAND: So I have a couple more questions. So one on the 7030, what do you think the timeline is at this point for bringing that forward? Like, where is it sitting at this point?

MS. SHEPPARD: Again, I am not trying to be difficult, but I don't want to talk about moving a 7030 group forward. We could talk about where we are at 7030

absolutely. I can give you high level updates. I will also say that you can go to x12.org, to the landing page at any time, mostly any time. We're trying to keep the schedule as updated as we can, and then we'll say we expect this in Q1 2020, we expect that in Q3 2020, so you can have a good idea of where we are in the publication cycle for those books. You have a specific --

MS. STRICKLAND: I'll say it a different way -- when do you expect your first iteration of your yearly transactions to come out?

MS. SHEPPARD: The first one is out. So we took the books that were previous to 7030, let's just say that -- I don't think there were any 7020s. The books that were already published and weren't being actively maintained exist now and they're in the technical report library, and they'll all been moved up to version 7060. So, for example, supply chain has a set of implementation guides. Those implementation guides were brought forward from 4010 to 7060 in the first iteration of the technical report library. So that's how -- that's going to keep feeding.

So as the standard the base standard changes, those base standard changes will be applied automatically into the technical reports, and then the technical reports will be available at that level. I'm not trying to not

answer your question, Deb, I'm just trying to make sure that we're clear.

MS. STRICKLAND: I'll stop pulling the string. I have an unrelated question. So as you're expanding your communication and your outreach, it's always difficult and we know it's difficult, but how are you going to sort of reach out to those unrepresented audiences, the ones that you can't get to now, it's a little tricky, they're smaller groups maybe. What is your plan for sort of a different outreach?

MS. SHEPPARD: Different outreach is hard. We continue to try to bring in small associations that represent small specific subsets across the whole ecosystem, to use the word that we're all trying to use now. We can only beg people to participate, and other than that we don't have -- we can show them the advantage, we can invite them, we can include them, we can say if you can't be here you can be in our survey group, and if people have new ideas on that, we're glad and happy to have them because we do a lot of begging and offering for input.

I do think that we have a greater number of those small very specific niche groups than others, because it's not an onerous price to participate, and so we can go to the naturopaths who only use three pharmacy lists and say, well, you guys want to come over here, too? We'd like you

to come over here as opposed to only talking to people who can afford to pay, you know, a few thousand dollars a month to participate in the discussion.

DR. STEAD: Are you done with the questions from the people that know what they're talking about?

(Laughter.)

I am going to ask a generalist question, but it's truly a generalist question. I'll pose it and then you can decide how to sequence it. It sounds like with your experience broadly, that other industries are not stuck as badly as healthcare is, and those other industries deal with regulations and law, just like we do. So, what's the takeaway for that from that? The idea of a purchase order transaction, without regard to what type of purchase order makes perfect sense to me since I don't need to live in detail, but I'm assuming it means the specifications are extraordinarily skinny and have some way of leveraging your other metadata tools and so forth to deal with some of the granularity. But I mean, but it seems to me that there must be a fundamental difference between the way healthcare has tackled this and the rest of the modern world, and I would just like to know what that difference is.

MS. SHEPPARD: I think the difference is time and memories, because we've got to remember that the TDCC was X12's predecessor, and it started in the early 1970s, and

it started in supply chain, retail, transportation, those industries, and of course I'm not nearly that old, but as I understand it, the first 20 years of that was as painful as this is for healthcare. Everybody wanted what they wanted, and they didn't really want to compromise that for the good of the larger group, and there was a lot of angst and a lot of disagreement, but over time it became clearer and clearer what the real requirements were.

So you might have a lot of things that you'd like to do with the purchase order, but do you really need to know that the order clerk's eyes were blue, no. So those requirements have refined over time until there's not really controversy about them anymore. But we're all younger than that. So what we see is the other industries are smoother and healthcare is not smooth. I think it's just a maturity cycle, but I also do think that less government regulation in those industries has been more conducive to actual cooperative back and forths where people are willing to give something up to get something and the result is something everybody can live with.

I'm not sure that the mandates have done us a favor in how much we're willing to actually sit down and compromise with each other. Also, in the other industries it hasn't been artificially focused, as Alix said, and you all know there's a select set of X12 transactions that are

mandated. There are other X12 transactions that are available and that are useful, and they could ease implementation burdens. But if you go talk to implementers, we're only doing what's mandated, because that ask is huge and the lift is heavy, and so we're not interested in improving the efficiency of our business in other ways.

So we've limited ourselves as part of our effort to focus ourselves. But I think it's all growing pains, and I think by the time -- are there any young people in this room, like really, really young, by the time the youngest person in this room is ready to retire, I think other industries will be looking at us and saying, oh, healthcare is so smooth. That's a wish. I can dream.

MR. COUSSOULE: I can add a little anecdotal information to that that's pretty real. We did our first EDI implementation for a big manufacturer in 1984, and if you think about that time, there weren't a lot of complicated systems in play. They were relatively new. The internet didn't exist, cell phones didn't exist, you were in a very different kind of world. So when it started up in healthcare, you had a whole different ecosystem that was already in play, so you get a bunch of ingrained parties that are not interested in changing things. That's just the reality of things, where the starting point went.

But I will tell you with the same kind of challenges in 1984 we dealt with, it was different every time we did it. So it's not unusual. It's not unusual, having lived through that.

MS. SHEPPARD: I think that is a great question.

MS. GOSS: I would like to talk about testing plans. On slide 23, you made a reference to GenRocket and discussing the tests and certification plans. Could you expand upon that?

MS. SHEPPARD: Not very much. We have a plan that we can't go forward until we have a better test suite, and stronger example set to build on. So, we have heard not just here but ONC, other federal agencies, across the industry, at WEDI, at everywhere, that the industry as a whole is interested in somebody else saying you got this right, and no one else can really say you got this right other than us. We need a test suite to start flushing that out. So when we have a test bed and expected results, then we expect to move to the next step which is now how do we make it easier for people to show us that they get these expected results from this input, these expected results in these situations. It is basic right now.

MS. GOSS: So the intention is to have work products or standards and technical reports that have corresponding test beds, and that then they'll be -- once

that capacity exists, you'll work out a process for engaging participants in either proving out their capacity to meet those requirements. Is there an expectation related to that process that would involve end-to-end kind of testing capacity across multiple stakeholders? Because what I heard -- maybe it's just because it's limited information at this point, I'm trying to tease out, are you looking to create a testing environment that lets me come hit up against a platform at X12 that says, yup, my system does what you expect it to, or is it that maybe I can test with Bob Phillips, you know, I'm the payer, Bob's the provider, we can actually get an EHR in the middle or some practice management system in the middle, and prove out that the test suite that you've designed in X12 works across that continuum from Alix across multiple systems and over to Bob.

MS. SHEPPARD: So what we want to do is we want to create a consumable path that we can actually do in a reasonable amount of time and then build on it. So we want to say to start with, we just want to be able to let you come in and see if you get the expected results that you think you should have, and then later, if that works out well, we hope that we expand it so you can get with Nick and say we'd like to test with each other and see if that works.

Somewhere along the way we know that there are at least some of the federal organizations that would like us to tell them if somebody has a compliant solution that gets expected results. But what we want to do is create a strong infrastructure so that then we can say, okay, we have this; now, would you like to use it this way or would you like to use it this way or would you like to use it this way. So I can't tell you right now what's going to come first between those functions, except that first we need to get a set of input data and expected results put together, and then we'll be able to listen to what the strongest need is and focus on that one. We can't do it all at once. We know our own limitations. We won't be able to provide everything to everybody at one time. So we'll build.

MS. GOSS: I appreciate that context. I don't want to do a spoiler alert about our upcoming recommendations. Stay tuned for after lunch, folks, because we have some very pointed thoughts about the need for testing. So it's good to hear your thinking and that you're working incrementally towards successful testing support within the industry related to your work products.

I've just gotten the time, so I will hold the rest of my questions.

DR. STEAD: Thank you very much.

MS. SHEPPARD: Thank you for having me.

MS. HINES: For those of you who ordered a sandwich, you can go down to that area on the ground floor, G on the elevator, and all of the food is waiting for you. If you didn't order food and would like to get some, I understand there's some on the first floor that a local restaurant brings in every day in lieu of the closed cafeteria, and then you can take that down to the ground floor.

There's lots of seating in various areas around there and Maya Bernstein has reserved an area for us. So please either go down and get your food or pick some up on the first floor on your way down. Technically, we are not supposed to roam this building unescorted. So federal staff will try to be with you, and we'll see you back here at 1:30, prompt.

(Luncheon Break.)

AFTERNOON SESSION

Agenda Item: Predictability Roadmap

MS. GOSS: Between the predictability roadmap section and the prior authorization, we will be taking a short break, although it's not on the agenda. We will provide for that opportunity. So we are going to start out with the predictability roadmap opportunity, and I'm going to be leading us through the slides.

Let's first start with an overview of this update, and a first thing we want to provide this afternoon is a refresh on the predictability roadmap work, which has been about increasing our overall capacity to meet the pace of business and technology advancements in our national standards framework. We want to discuss the outcome of our July visioning workshop related to recommendation 5 in the letter we sent last February and our subsequent discussion that we had with the Division of National Standards, along with the follow-up to the visioning session that we performed in producing a letter with new recommendations that we anticipate vetting, and hopefully we'll have approved today.

A little bit of background and context. The issue of predictability in meeting the industry's needs for upgraded standards has been a longstanding topic. We implemented our first round of HIPAA in the 2003 timeframe,

with standards development organizations responding to the need for expedited modifications and working with the feds to adopt the errata, affectionately known as 4010A1. That process produced some industry feedback and recommendations to the National Committee for Vital and Health Statistics, resulting in some recommendation letters to help address the industry concerns related to barriers for updating and adopting standards.

Additionally, throughout the timeframe from 2006 through 2018, we've been providing regular reports to Congress, as required, including commentary regarding the slow standards development publication and regulatory processes, which all leads to a lack of predictability for the availability and adoption of standards. It's hard for business to plan, to know when they need the resources and need to make modifications to their workflows and processes, without the reliability of knowing the schedule on which standards will be available and adopted.

The administrative simplification provisions under HIPAA in the Affordable Care Act has provided many benefits and improved the overall status of electronic information exchange between covered entities. This has been affirmed throughout our efforts in the last couple of years, but there still remain significant barriers related to the development, adoption, and implementation of

standards, not keeping pace with the evolving nature of our healthcare industry, and that barriers and challenges exist at each stage of the process: standards updates, the evaluation of standards and operating rules, federal adoption, and industry implementation.

The barriers were really elevated as a part of NCVHS's review committee work in the 2015 and 2016 timeframe. We did a retrospective on the mandated standards, and it really underscored the criticality of creating more predictability in the process. As such, the subcommittee took on a very focused body of work which we affectionately refer to as the predictability roadmap. Started out in 2017, with project scoping efforts and meeting with the standards development organizations and operating rule authoring entities, to ensure that we had a clear and appropriate understanding of how those organizations functioned and how they developed their standards, which were then being adopted as United States standards.

We undertook an appreciative inquiry, visioning workshop, on HIPAA's 21st birthday, and I think it was also a solar eclipse. It was quite a monumental day. We then went from that workshop into having a more of an end user's focus by holding a CIO forum, representing our industry and federal partners. We've been doing outreach and awareness

to promote the body of work that we've been undertaking with stakeholder groups and soliciting extensively input on our draft recommendations.

When I refer to the draft recommendations, I'm referring to the 23 initial recommendations that we put forth, I think, in September of 2018. We then held a formal hearing in December of 2018, leading us to developing a narrowed scope of recommendations. It's always a balancing act of what we would like to do versus what we think is realistic to accomplish in the current environment.

That letter was sent in February of 2019 after being vetted with the full committee. Those five recommendations included recommendation 5, for the designated standards maintenance organizations' role in advancing national standards being reconsidered under the current light of day, as to what was needed as we would move forward, with regard to how that organization could help advance the objective of more predictable readiness and adoption of national standards.

In addition to a visioning session that we held this past summer in July with industry experts, we met with the Division of National Standards to discuss the five recommendations advanced in February, and also to get

feedback from them on the visioning session to identify additional opportunities to improve the overall processes.

That kind of gives you the high-level view of what we've been up tot for the last several years. Let's talk a little more specifically about the visioning session in July 2019. This was related to recommendation 5, which was to reevaluate the function and purpose of the designated standards maintenance organization, affectionately referred to as the DSMO. DSMOs, for those of you who may not be familiar with them, are three standards development organizations and three code content committees. They're responsible for maintaining and updating the standards and code sets and advancing recommendations for those standards to NCVHS for consideration, whereas, just for clarity, operating rules come directly to NCVHS for consideration.

There is a memorandum of understanding among the six organizations, and that's been in place since it was created in the early 2000s, and we had originally envisioned that the change requests in the United States for modifying our standards would all go through the DSMO process, and then come forward through the standards development processes, and then ultimately artifacts would be vetted back again through the DSMOs before coming to NCVHS for consideration. However, the reality was that the

industry early on just started to go directly to the standards bodies and make those change requests.

As we got into the visioning workshop, we prepared for it in a way that created a problem statement, and we set a framework, thanks to the talented resources in the innovation office in HHS, who facilitated the visioning session. We found that the conversation went in a variety of directions. So we started out with wanting to address the barriers that exist for industry to adopt and implement updated versions of standards, implementation guides, or operating rules on a predictable, reliable, and timely basis, sufficient to meet the evolving business needs of industry, trading partners, and their business associates.

The outcome of the July visioning session, combined with the input of other stakeholder events, yielded consistent familiar themes, not necessarily focused on how does the DSMO need to change, but more about how the ecosystem needs to evolve as a whole.

Let me first talk about some of the consistency and all the themes from the stakeholders. These are themes not just from the visioning session, but they were certainly underscored during the visioning session. There's definitely a need for the evaluation of updated or new standards and operating rules. The SDO and operating rule authoring entity processes for development need to

include testing as well as the publication efforts. Ability to use standards on a voluntary basis needs to be promoted, as that will support innovation. We need to expand stakeholder engagement in standards development. Those who can pay to play are there, but there are a lot voices that need to be reflected in our national standards, and we need to find a way to better engage them in the process, to understand their business needs, and have standards that will meet the broad depth of situations in our market.

Enforcement. We have carrots and sticks, but from the enforcement process we also learn, and those, the enforcement efforts, help us improve the consistency of the implementations. Predictability in standards is needed to help the marketplace. And that the regulatory process needs to help expedite access to standards.

The visioning session made it really clear that industry wants us to do something and do something now. They've been having these conversations for decades. I was part of the group that presented the 2006 recommendations to NCVHS on how to improve the process based upon the initial implementation, and so it's been an honor to try to advance the process now, and I think we've heard loud and clear that we need to do something. So we've focused on what we think are the short-term opportunities for actions.

These are tough topics, very complex topics. We would have solved it 20 years ago if they were easy. So what we're trying to do is take some very strategic, incremental steps forward in the body of work that we're going to be advancing for consideration by the full committee today.

Before we jump into that letter, I would like to share some of the feedback that we received form the Division of National Standards regarding our February letter. We did receive a response, and it is posted, I believe -- Rebecca, keep me honest -- it's posted to our website. They responded to our February 2019 roadmap recommendations on June 4, and, in addition to discussing their response, we talked about the visioning session, and what opportunities might exist for us to improve the processes. So it's important to understand that that conversation happened, because it did influence some of our thinking as we moved forward with the visioning session results, in how do we target actionable recommendations that could have an impact quickly, if they were undertaken.

To set a context for the letter that we're going to advance to the full committee for review and approval, I wanted to cover the findings from the visioning session, and the basis on which we created the recommendations. The first finding is related to rulemaking as a prerequisite to industry's use of updated national standards. Without

rulemaking, the industry doesn't want to move. They've become trained and responsive to the federal hammer, so to speak, coming down and saying this is now the new law, the new standard, let's move forward. They're hesitant to make financial and operational investments to test or use an updated or new standard without a federal mandate.

The current pathway for HIPAA-related rulemaking is not meeting the needs of the U.S. healthcare industry or federal policy objectives. Procedures around rulemaking should be optimized, since we've been clearly told we can't get rid of those processes.

MR. LANDEN: Let me just chime in on the previous slide. That middle bullet, I think the key statement throughout this is that the HIPAA-related rulemaking is not meeting the needs of U.S. industry, and that's the reason why -- you recall the early slide -- the industry is telling us to do something and do something now.

For some context, the industry is very solid, there's a very solid base of value underlying the HIPAA standards. If you look at the 837, particularly the claims transaction, industry has migrated to that, and the efficiency with which industry processes claims and makes payments has been just phenomenal under HIPAA. But it's keeping up with the changes and now starting to move to some of the less financially visible transactions that are

obstacles to the industry, and how HIPAA needs to evolve. So the recommendations that we're talking about here is talking about that collective evolution and that the federal rulemaking process, while necessary, and even valuable for the industry, is also a barrier at the same time. So we're wrestling now with ideas about how we optimize that and still stay within the federal Administrative Procedures Act.

MS. GOSS: The second findings related to the adoption of updated HIPAA standards must come more frequently, more predictably, and more reliably, in smaller, more easily assimilated sets. The waiting every 10 years is not really helping the industry. There also needs to include a value proposition to support their adoption, and in order for the Administrative Procedures Act processes to work effectively or efficiently, they need qualitative and quantitative data from the SDOs and the operating rule authoring entities about the testing results from use cases, expected benefits and return on investment, to include in the impact analysis of the regulations in order to successfully complete the rulemaking processes.

There's a regulatory impact analysis that the federal rule-makers must complete as a part of their rule promulgation. So we need to make sure that they're armed with the right data to be able to get through that process.

It's a big barrier to them in being efficient if we don't have the right data. That also means that we need to test and really prove out and have experience with a standard to be able to get that quantitative and qualitative data.

The third finding, end users of the standards, especially small clinician offices or their representatives and public health agencies, do not have the economies of scale to participate directly in the current standards development processes. A lot of the time, people that don't participate in standards development, wait until the federal rulemaking proposed rule comes out, and at that point the standards or the operating rule is baked. It's done. It's too late to go back and update that.

There are three recommendations that we're going to be going over shortly, so let me tease them out here, and then we're going to pivot over to Rebecca, and we're going to then look for a full committee review and approval of the letter and also talk about what's going to be next for the subcommittee on this topic.

The first recommendation is for HHS to provide guidance on the data needed to support adoption of standards and operating rules. We're asking for clear guidance regarding the data and the quality of the standards needed to support the adoption in the rulemaking processes. We also want to have provided clear and

specific guidance regarding requirements to test new or updated standards.

Two, secure support for testing and evaluation of standards and operating rules. We believe that HHS needs to find a funding stream to enable effective testing. Three, facilitate a more nimble approach to standards development with broader industry engagement. We need to find a way to get a more diverse representation of stakeholders at the table.

Before we move into review of the letter and hopefully approval, I wanted to put a placeholder out there that the subcommittee is committed to working on a longer-term vision over the next year, with consideration of industry input, proposed and final rules released by HHS, and standards convergence efforts from ONC and HITAC, and that we think that there are more opportunities for improving the process from a longer-term view, but we need to do some more engagement. We have a couple pieces that need to fall into place.

We've got a lot of those irons already in the fire in our collaboration, as you'll hear later this afternoon, related to prior authorization, so that as several things occur over the next three to six months, including NCVHS's workplan development for 2020, we'll get greater clarity on the longer-term vision work that we need

to do and complete the necessary corresponding project scoping statements.

Before we switch over to the letter, I want to see if there are any questions. I also want to make sure that our members on the phone chime in and let me know if you have any questions or if you're good to go.

DR. STEAD: Back up just a second to the recommendations, just because I think if people really understand the way they fit together and what you're trying to do at this level, then the letter really becomes a matter of are we wording it correctly. Because I think what the standards subcommittee has really tried to do is say what are the things that we can just do now within the existing processes that would shift everything forward in a way that would, in fact, both increase predictability and take time out, because we're no longer doing so much after the fact.

The first recommendation is we need explicit guidance from the Department so that the standards development organizations can make sure that as they're doing the work, they collect the data that will be needed to drive the decision-making process. I think it's that simple, is what that recommendation is providing. And then take the questioning out of the way of people that want to work on new and emerging standards and to make it so that

through a registration process or whatever, that's easier to do. So both of those are things that as far we know could just be done, that if we had that clarity up front, would move everything forward.

Is that a simple way to describe that? I'm trying to make sure we understand the true --

MS. GOSS: I'd add a little color commentary onto the testing and evaluation. We've already asked HHS to promote awareness of the capacity in 162.940, which is the ability to request an exception to test a standard that is not already promulgated. We want them to continue to do that, promote awareness, engage industry in being willing to test, but what we've really come to understand is that that's not enough. We need actual support to the industry to ensure that testing and evaluation of those happens before they come even to this table, so to speak.

DR. STEAD: And the certification and so forth you're doing is recommendation 1 sub-bullet 2.

MS. GOSS: No, I'm sorry. I was clarifying number 2. I didn't -- I thought you were covering both. My mistake.

MR. LANDEN: Back on number 1, so bullet 2, what we have got now is a regulation that allows industry to do the testing, but we want to shift that from -- we can tolerate this exception to proactively utilizing that

exception and actually preaching it to the industry to go out and be a positive vehicle to test innovation and to test the emerging evolution of the standards and operating rules.

MR. COUSSOULE: Just one more color there. The idea of testing is kind of mentioned in two things, but in the second number 2, it's really more about supporting the creative testing of new things, and in number 1, it's more about what is necessary inputs so that the process within the regulator work better and faster. So it's like as much information as can be provided, which include testing information, including value and benefit information, et cetera, would be provided, such that that process wouldn't be hamstrung.

DR. STEAD: Are there other questions that we need to -- people want to ask just to make sure we're correct on the intent before we go into the work, make sure the wording is okay?

MS. GOSS: In our typical fashion, what we would like to do is walk through the letter, solicit input from the members. We're going to walk by paragraph. So the opening is first paragraph up for consideration. Are there any comments?

Denise, I see your tent card go up. Just put your mic on and let us know what you would like to suggest.

MS. LOVE: Well, first off, I think it is well done, and I think the letter as it's written doesn't warrant too much, in my opinion, comment, but as I read it I'm just asking the question of you all, do we need to convey a sense of urgency in that first sentence to the extent that -- and I'm not sure who is reading it -- convey that there's a sense of urgency in the form of there's an urgent need to update our nation's information infrastructure -- I'm just throwing it out there -- to meet the needs, growing need, for timely cross-sector information. This requires immediate action. Or is that too much?

The rest of the letter I think reads very well and dovetails with my understanding of the recommendations and the explanations. So I'm just asking the question back to you. Is there a need to put something that conveys a sense of urgency in that, because as I read the letter, I didn't sense that it was that pressing. That was my interpretation.

MS. GOSS: I would open that up for subcommittee discussion. How do people feel about that? I have looked at this letter so many times, I don't know that I'm the best person to answer that question.

MR. COUSSOULE: I think if you look down even, skip down a couple of paragraphs, right there, where it

even talks about that emphatically asked the committee to do something and do it now. I guess the question is that -- I think if I'm understanding you, Denise, is should that be strenuously made earlier in the document, or does it get buried in here?

MS. LOVE: It was more of an opener to get the reader's attention. But again --

MS. GOSS: I would entertain specific language for consideration, if you have any.

Rich?

MR. LANDEN: Just a comment. I think we need to strike a balance between a sense of urgency, which I believe there is, but short of a crisis, we don't want letters to start the sky is falling. So depending on language we come up with, I'd be conceptually willing to convey that sense of urgency as long as we don't go too far with it.

DR. CORNELIUS: What about merely underlining the text that says participants emphatically ask the committee to do something and do something now?

MS. GOSS: I like that solution.

DR. CORNELIUS: Some kind of highlight.

MS. GOSS: Any objections to emphasizing that in the bold as has been done? I think that's probably a good addition.

Could you scroll back to the top? I think that one of the things that we've heard is that industry has been very frustrated that they've made recommendations, not only in 2006, 2009, 2015, plus all of our recommendations to Congress, and still stuff is not getting -- the process isn't improving.

DR. STEAD: One question. What would happen if you change new to pragmatic? Is there -- I'm just wondering if that would help. I don't -- this is a fresh letter. If you have -- this is about how to get somebody uptake. Anyway, any suggestions would be appreciated.

MR. RUCKER: Yeah, and looking at what I've seen of the letter so far and at the slide deck, I think it would be helpful if there were specific cases, right? Because the slides have -- you sense there's a process that's not working, but sort of some real world cases, I think, would be -- we can't do X, because of this, or this has failed, or in a modern world, the following circumstances have changed, and I think that makes these things, specifics makes this -- because the Secretary, you know, we have had some discussions and unless you have very pragmatic things for people who don't live this, so that would be one suggestion.

The other thing that we've run into in our rulemaking is under the -- I don't know if this falls under

this, it may or may not, under the administrative procedure act, we wanted to have some sort of version updates, right? On some of these standards, and we were told by the Office of General Counsel that we cannot -- unless it goes through the notice of proposed rulemaking process, we cannot have like version 3.2 cannot just go to version 3.3, and there are some things that I think have been batted around that everybody knows about, like the NCPDP script standard and various versions of that, even within HHS. So it may be part of the ask here may be some rethinking of the Administrative Procedure Act, which I think requires some congressional activity. We floated an A-19(?) on this. Those would be my two thoughts.

DR. STEAD: Thank you, because the latter is more the kind of thing we're talking about as next steps. We're trying to get the things we put in this letter to be things the Secretary could just do that would be -- they could just do, would move the process forward and help the industry, and buy us time to do the things that involve legislative change, et cetera.

MR. RUCKER: Yeah, you may be under a totally different authority for this.

MS. GOSS: All right, so we've made two changes now, pragmatic in the beginning -- oh, go ahead, Rebecca.

MS. HINES: I just wanted to, picking up on Denise's suggestion, I think there is an opportunity in this bottom sentence, participants emphatically asked, to add something, if we can come up with specific language in there, before we launch into our earlier findings, to emphasize this and perhaps even do a footnote to a case example or something, to make the case why this is not just a run of the mill kind of recommendation. That was just something we could look at.

MS. GOSS: I'm pondering that idea. Let's go back to the top of the letter, please. Okay. So opening paragraph. Good discussion. Any other comments on that one?

(Laughter.)

It's always helpful to give specific suggested text. So then below the opening paragraph, we just have the three recommendations summarized. Hold that thought. We're going to get down to that paragraph, because I think that I'm going to take your idea, with Don's idea, with Rebecca's idea, and I think we are going to focus on the participant paragraph in a moment. So let me just get through this next paragraph, the genesis, if you could scroll that up.

So we have the three recommendations we've already reviewed. So this next paragraph is context setter

for the reader, that these are new recommendations based upon our engagement with the stakeholders in July, to explore our February 2019 letter related to the DSMO recommendation.

Are there any comments on this paragraph?

(No response.)

So let's go down to the next paragraph. Participants emphatically ask the committee to do something and do it now, to speed the availability of updates for use. So I think the suggestion was maybe some kind of urgency sentence can be put in there that these are short-term actions that could be undertaken to improve the effectiveness of future standards used in the United States.

MS. HINES: Or to use the use case, have the urgency why industry is basically -- this is so urgent, because it's really mucking our entire business process up.

DR. STEAD: Tie it into patient harm from prior auth.

MS. HINES: So you've got this idea, and then we move right on to our earlier findings. So there's an opportunity there to expound on that first sentence and footnote a use case. Why so urgent? And use some of your language, Denise, so that way it's a win/win. We got the

urgency, we've got the use case, and boom. Summary findings.

MS. GOSS: So would it be amenable to the group if we were permitted to work on that offline and continue through the rest of the letter? Because I can't pull that off at the moment.

All right. So next paragraph -- oh, wait, before I do that, anybody on the phone have any comments, concerns?

(No response.)

Okay. So summary of findings, this is the next -- this paragraph and the following three bullets reflect the content that I reviewed during the PowerPoint. So are there any comments on the section summary of findings? The opening or the actual three bullets?

If I hadn't noted it earlier, just for those who may be listening in or observing the session, this letter was sent out in advance to all the members. So it's not their first time seeing it. They had the opportunity to review it as part of their prep work.

I'm seeing no comments and I'm hearing none from the phone. Could we now go to the next page essentially, or section, would be context for NCVHS's recommendations? So this is where we start to dive deeper. We not only repeat the recommendation, but then we give background

context around it, and what we're asking for, in this case HHS developing and publicizing its review criteria for updated and new standards that national standards or operating rule products should meet to comply with the principles of HIPAA and support federal rulemaking requirements. That guidance would enable those organizations and the industry to build meaningful research and analysis into its development cycle. Processes to capture and compile information during the development and testing phases could be implemented or approved.

So we are looking to receive more details from the feds so that the industry can provide us with better information before it comes forward for consideration of adoption. Any comments on recommendation one?

Seeing and hearing none, let's move to recommendation two. Secure support for testing and evaluation of standards and operating rules prior to adoption. This is about finding a neutral funding stream to support the testing of administrative standards to enable the detailed evaluation of value and return on investment prior to any recommendation for adoption. Funding stream would support testing and proving grounds, specifically to assess the readiness for national adoption. We do indicate that we'd like to see this be end-to-end testing. Any comments on this recommendation?

Okay, recommendation three is to facilitate a more nimble approach to standards development with broader industry engagement. We'd like to see HHS engage in regular communications with the standards community to support their efforts to develop smaller, incremental, and more frequent publications of standards and operating rules, support the standards organizations as they create more sustainable and dependable processes. Further, HHS should engage a broader base of industry end users to evaluate SDO products before they are finalized. Such organizations would include the small providers or their vendor representatives, state and local public health agencies, and small health plans, which are typically absent from the standards development processes.

Any comments on recommendation three or the two subpoints?

And then we have a standing closing that we have used in this. Are there any comments?

Okay, so what I've heard is that we want to make a modification on the bottom of page 1 to emphasize the criticality and urgency, and hopefully correspond to a use case underpinning the reasoning and that we can do that subsequent. So I would like to, if people are okay with the ability to move forward with modifications as such, and then we can -- from a due process perspective, do we need

to handle this like we did the ICD-11 modifications this morning?

DR. STEAD: I think there is enough agreement about the content of the letter, that it would be good to go ahead and approve a motion to accept the letter and to have -- you know, add the text related to urgency, and if we don't get that where we can vet it before we leave here, vet it with the executive committee. So maybe we say vet it with the executive committee so there's no reason why we can't try to do it while we're here. I would go on trying to get the motion approved today, if we could.

MS. GOSS: So we are looking to have a motion to accept this letter with a modification related to the participants paragraph, to reflect the urgency of the situation, and that if we're unable to bring it back for full vetting with the full committee, this meeting, then the executive committee will be delegated responsibility for reviewing and approving on behalf of the full committee.

MR. COUSSOULE: I will make the motion.

(The motion was duly seconded.)

MS. GOSS: Thank you. So we have a motion and a second. Is there any discussion? Any comments from the phone?

(No response.)

Okay, sounds like we're good to go. All right.

DR. STEAD: We have a motion, and we have a second. All in favor?

(Ayes.)

DR. STEAD: Any opposed?

Jacki, were you voting in favor or were you voting against?

MS. MONSON: In favor, of course. I don't want Alix to be stressed out.

(Laughter.)

MS. GOSS: Okay, good. Motion carries. We'll work on that revision.

DR. STEAD: Congratulations.

MS. GOSS: So we're ahead of schedule.

(Pause.)

DR. STEAD: If we have the -- if everybody's here, can we just proceed with the agenda?

MS. GOSS: And then have an appropriate point for a break. So what I would like to do is to be able to do the setup. So we'll need to pivot to the next set of slides for the prior authorization. We do want to provide some context and some level setting, and then we can -- and then have Don have the opportunity to make comments, and then we'll invite the panelists up, unless you want to do that logistics now.

MS. HINES: Why don't we do the opening and then take a break.

MS. GOSS: Okay. So could we have the prior authorization slides, please?

I am going to take the lead on this, but my esteemed co-chair Rich is going to chime in and keep me honest on making sure we cover all the key points here today. We really wanted to set some context about what led us to have this session and where we're headed, but we also wanted to provide some educational content to make sure people were level set on what prior authorization is about, because it differs between medical and pharmacy as far as the standards that are in play.

So from a 21st Century Cures Act perspective, ONC's federal advisory committee HITAC and NCVHS are to engage and collaborate, and that our recommendations shall be considered in the development of their policies. In March of this past year, this year, the NCVHS subcommittee on standards participated in a health information technology advisory committee, or HITAC, meeting around the topic of prior authorization.

In addition to the work that's those two points, we have developed a joint collaborative project scope related to the convergence overall of administrative and financial and clinical standards, and so prior

authorization is the shiny object related to convergence. So there's a larger umbrella of convergence collaboration that we have been discussing with ONC, but front and center in that is the need to improve how we handle prior authorization and so March's events really showcased that collaboration, and then we continued it in June where ONC participated in our June full committee meeting, and we have been continuing to have discussions throughout the summer to set ourselves up for today's listening session.

We decided that there was a need to really get an update from the industry on their prior authorization work. Since March we had a tremendous set of panelists. In March, give us an update on the various efforts and initiatives and we felt that there was a lot going on since that March event. So we want to learn from the industry activities related to their surveys and standards development and testing efforts, so that we can also make sure that we understood any new gaps or issues that may have been identified, and that this would help support next steps and workplan scoping. HITAC and NCVHS as federal advisory committees are both looking at their 2020 scope of work, and that certainly for all of us includes the collaboration between the two standards bodies' federal advisory committees.

MR. LANDEN: As we learned at the March joint meeting that the subcommittee attended at the HITAC meeting, industry has a lot of activities going on in the prior auth space, and they're moving rapidly. So some of the things we need to keep in mind is number one, how do we stay out of the way? And you know, let the industry do as much of this themselves as they can. Number two is how do we help remove barriers that the industry can't remove for itself? And then number three, what other things can we do to help the process along?

So it's not so much that we need to do something. It's we need to facilitate industry doing what it's already heavily engaged in doing, and then making sure that what they come up with is scalable to the extent that industry needs for national implementation, and then format it in such way it's consistent with the legislative and regulatory requirements, and that's both on the ONC side and NCVHS side under the HIPAA and the other legislation.

MS. GOSS: Since not everybody lives in the world of prior authorization, we thought it might be important to set some context around what is prior authorization. These slides will certainly be made available for folks to look at in detail. They'll be posted.

But let's just go ahead and summarize what prior authorization is. It's an administrative process requiring

a healthcare provider to request approval from a health plan for a medical service. The authorization has to be obtained in advance, and from the health plan's perspective, the purpose of authorizations is to prevent potential misuse or overuse of services, control costs, monitor care coordination. Authorizations are often required under benefit plans to support payment processes.

There are standards for prior authorization in terms of how the providers and the plans exchanges information electronically. These standards are adopted from rulemaking authorities, so on the next slide, on this slide, we want to give you kind of a summary of those authorities.

So HIPAA standards are adopted by the Secretary of HHS. The authority has been delegated to the Division of National Standards at CMS. HIPAA applies to all the covered entities, providers, payers, clearinghouses. Under HIPAA, our committee, NCVHS, has a role in making recommendations regarding the standards to be adopted. In contrast, electronic health record standards and EHR certification are under the authority of the Office of the National Coordinator.

New standards, such as HL7's Fast Healthcare Interoperability Resources being proposed for adoption -- Information Resources, sorry. I should know that. Are

being proposed for adoption under several authorities at HHS and CMS.

The CMS proposed interoperability rule will affect Medicare Part C, D, Medicaid, the exchanges, and Medicare healthcare providers. ONC is also proposing new legislation to adopt standards of HL7's FHIR part of the 21st Century Cures Act for EHR certification and interoperability.

So some pharmacy standards for electronic prescribing for prescribers are adopted under the authority of CMS part D program under Medicare. The Medicare program writes these regulations, which impact Medicare prescribers of controlled substances.

Additionally, other pharmacy standards fall under the authority of HIPAA, which again is under the purview of the division of national standards. So clear as mud for everybody? The point is that it's a complicated landscape. We have Division of National Standards, we have ONC, we have CMS. They're all within HHS, but they each have different roles and responsibility in advancing prior authorization, whether it's for a medical service or a pharmacy med.

Now that I've put most of the room to sleep, because you guys could all teach this, okay. Clear as mud. All right.

So under HIPAA, we affectionately refer to the 278 transaction. It's really the referral certification authorization transaction, as adopted under federal rulemaking, for the original, for HIPAA, and its updates. So this covers a request from a healthcare provider to a health plan, requests from a healthcare provider to a health plan for a -- so we have review and authorization and then response, according to the request.

So side by side, let's just try to do this visually to help people understand the difference between HIPAA and Medicare part D. So HIPAA covers the medical services for the 278 transaction, which is the X12 for medical prior authorization transaction and implementation guide. For retail pharmacy drugs, it's the NCPDP D.0 telecommunication standard, although I will note that 18 months, 2 years ago, we made a recommendation to HHS to adopt NCPDP version F2. I understand that might need to be F6. But maybe that's a use case example, I'm not sure.

Okay, so Medicare Part D, CMS has released a proposed rule to adopt a standard for electronic prior authorization between prescribers and pharmacies. NCPDP version 2017071 SCRIPT standard is what's used -- it's known as ePA between the prescribers and the pharmacies, and the adoption of the standard is required under the

SUPPORT Act of 2010. HIPAA payers and providers, Medicare Part D, prescribers and pharmacies.

So HIPAA uses electronic data interchanges, promoting interoperability leverages application programming interfaces, Fast Healthcare Interoperability Resources. In some cases, providers use fax, phone, and mail, and the dreaded portals.

(Laughter.)

Every day, in some cases. As Bob Phillips is saying, for those of you who can't hear him, the reality is 278 is really not used, and we have been hearing that extremely consistently over the years. It's got a low uptake, and really, it's the phone, fax, the mail, and the portals that are really taking off as far as how the prior authorization function between payers and providers is really happening today. The pharmacy industry is using the SCRIPT standard on a voluntary basis.

So that's the landscape of today, despite our best intentions of adopting national standards.

DR. STEAD: It would be useful probably to have a table that goes along with that that basically says what percent of the transactions flow through this and what do not.

MS. GOSS: Yeah, didn't we do some of that in our report to Congress?

DR. STEAD: We did. I'm just saying -- no, we did. I think the challenge, the thing that we communicated or we discovered during that conversation and communicated there is the data that we have on utilization tends to be the data on utilization for the transmission itself, regardless of whether -- how that transmission gets done. It doesn't in fact involve taking the transaction seamlessly from the provider's EHR, if you will, because you have the revenue cycle and you have the EHR on the provider side, and you have the payer system over here.

So in essence, the complex -- part of the complexity is that even when people are using this, it's not connected into the things on either end in anything approaching a standard interoperable way, and I think that's one of the things we're not able to -- we're not probably succeeding in communicating to policymakers is for this actually to affect patient harm and cost, it actually has to work end to end. Otherwise, in essence, we add complexity, making different little pieces of it work.

Somehow through this whole conversation, we're not yet communicating that lesion, I don't think, in a way that's actually connecting to people like my senator.

MS. GOSS: So another way I might put that is that under HIPAA we're permitted to use portals for direct data entry, as long as the content complies, but what's

happening in that -- whether it's a 278 or a portal -- is that the information flow is not traversing the work flows and the systems of those who need this information to advance the care to the patients to get the outcomes and to protect -- and to get the safety level that we desire.

So we'll listen to the transcript, we'll capture that sentence, and we'll add it to the next slide deck, I think is the follow-up action item.

MR. COUSSOULE: Bill, if I understand your point, it's we could make some amount of changes throughout the path from patient need to completion, but unless you look at it from the beginning to the end, you're not going to get there from an automation perspective. Otherwise it's just adding overhead into the process, right?

DR. STEAD: That is in essence why some of the fragmentation is really problematic. So I hope I'm not taking you on a tangent. I'm still -- I keep coming back to how can we really address this, and part of that involves making sure we really get at what the root cause or root lack of understanding is that's allowing this to be this wrapped around the axle.

MS. GOSS: I suspect we'll have an opportunity to take a deeper dive in that with our panelists today.

Bob, did you want to say something?

DR. PHILLIPS: The variability is really what is so frustrating, because one, you don't know that you need a prior authorization usually when you're starting to make a request for a medication or for a service, and then when you find out, you're not sure which process that person on the other end needs for you to submit it. You send it, but you don't have faith it's been received. So you have to set up a process to follow up, usually by phone or fax, to find out it was received in the proper way. It's such a complex cycle to complete.

MS. GOSS: Yeah, I think the complexity of the cycle to complete it is not also -- there's a check and balance that's going on in that system, and it's frustrating for, I think, for either end, but we have to always in my mind keep focused that there is a patient in the middle of this that needs to be taken care of and needs to be able to afford their healthcare and not be put into a financial burden themselves, without that kind of advanced knowledge of what their liability could be and whether it will be covered. So that's definitely a balancing act.

So let me run through a few of the prior authorization challenges that span all of the stakeholders. This is a compilation of past testimony. It is a top ten hit list, so to speak, and may not be a complete and exhaustive list.

Adopted HIPAA standards have low utilization rates, in this case the 278 is what we are talking about in particular. Inefficient workflow, dynamics related to the standards. Technical barrier issues with products and services. Payer-specific requirements are highly valuable, and that impacts the providers. There are regulatory inconsistencies, you know, the different sides of the house promulgating different rules. Prior authorization leads to an impact to the quality of the healthcare delivery. We don't have a vendor support or integrated platforms. We may have state mandated inconsistencies.

There's the impact to wellbeing and patient safety, certainly not at the bottom of the list because of importance, but because that's what I wanted to leave you with as we think about -- as we wrap up a few more of these educational pieces and lead us into a break. I'm just trying to cue up that I'm going to go to -- after Don gets to talk, after I finish this up, Don will go, we'll go to a break, and then the panelists can all come up.

But I want to make sure we also hit the authorization challenges related to pharmacy. In prior testimony, we have heard that providers and prescribers rarely use the adopted NCPDP D.0 telecom or 278 transaction standards for prior auth, even though they are mandatory transactions. They're really using SCRIPT ePA, payer

portals, or fax. Pharmacies may use the D.0 telecom standard to request an authorization from a payer or a health plan, if the payer has a policy in place to allow the pharmacist or pharmacy to obtain the authorization.

I wanted to make sure everyone had perspective on sort of the lay of the land. It is a little complicated. We know you don't all live in this world as much as the standards subcommittee does. So thank you for listening to that overview. I will take Nick's question and any other questions, and then I would love to hear Don's remarks before we go to break.

MR. COUSSOULE: Just quickly, I think it might be useful to explain the term mandatory in this case, because it's not entirely obvious what mandatory means in this sense.

MS. GOSS: Mandated by law, by regulations.

MR. COUSSOULE: Right, mandated by law and regulation, but there's ways not to -- you don't need to use it if you're doing electronic transactions in certain ways.

MS. GOSS: So we should have probably said mandated, not mandatory.

MR. COUSSOLE: I'm just saying it will help people understand that distinction.

MS. GOSS: Yeah, so that phrase, just to add, to respond to that, was that mandatory was really mandated per federal regulations.

Are there any questions on the phone or in the room before we advance to Don's remarks?

(No response.)

Okay, so I think we want to make sure we introduce --

MR. LANDEN: Let me just make one comment before we go on in that, again, historically, since I'm the designated old person on the group, the 278, the referral certification authorization transaction, back when that was first initiated and we actually have to go back, not the regulation, but the legislation, which was enacted and signed in 1996, but that legislation was based largely on WEDI recommendations from 1993 and 1994.

So that's the era at which this prior auth transaction, the 278, was developed, and at that time, you think of what the state of the art was, and it did not have electronic health records. It did not have automated processing algorithms on the payer side. So it was largely a vehicle to take a data dump and get it, move it efficiently from the provider office to the health plan, the payer.

That's not where we are today. So in a sense, evolution has overtaken this. I suspect that's one of the reasons why the uptake rate of the 278 has been so abysmal, but that's also the beauty of this whole collaboration process around prior authorization and we get to rethink the whole process, as several people have pointed out, and think it through end to end, given existing technology and our expectations for where technology is headed.

MS. GOSS: Thank you for the context.

So it has been a joy over the last year to collaborate with ONC and Dr. Tom Mason is their chief medical officer within the Office of the National Coordinator, has really been front and center in ensuring that we continue that collaboration and prepare for these sessions, and so we're very grateful that you're here today, Tom, and so we want to also turn it over to Don Rucker, who is the national coordinator within the Office of the National Coordinator, with health information technology within the Department of Health and Human Services.

Agenda Item: NCVHS and NOC/HITAC Prior Authorization Collaboration

DR. RUCKER: Thanks, Alix. So this is a nice slide deck. It is, of course, a little depressing when you look at it.

(Laughter.)

Though it's not as irritating to us as I think it is to providers and patients on a daily basis, and I think Rich's points are really spot on, that if you look at the history of this, we didn't have anything really to speak of clinically, electronically, when this started. I see our colleagues from WEDI in the back there, and so now I think we have a chance to take two things that before, one is the financial or administrative transactions, which has existed as we know since 1996, and now we can think about how do we merge that with clinical information, because I think it's the uncoupling of the financial and the clinical information that's really the root problem here.

Frankly, it goes well beyond prior auth, right? It really is the issue of how do we buy healthcare. The whole conversation about value-based care is really a sort of a -- I think it's a very goofy conversation. In our private lives, we would never do electronic shopping without knowing both the price and the product, right? I mean, would we ever buy anything from pick your favorite online site, if you only knew the product or you only knew the price? In healthcare, that's routine, and of course, the carnage in the public is massive.

So I think that's the underlying problem that needs to be solved here on one aspect. Then when you look

at some of the specific things that are generating the burden, right, the sort of lack of real computability, Tom and Andy Gettinger, our chief clinical officer, working with our colleagues in CCSQ, under the Cures mandate, we're required to do a report on provider burden. I think a couple things in that report stood out from Tom's work, and the three that I sort of saw that it's worth noting what we're trying to solve in each of these, because parts of government are working each of these. I think the biggest one, which is not necessarily an NCVHS thing directly, NCVHS thing directly, is that the goofiness of documentation.

So having all of these notes be this sort of the E/M coding, the level 4 and 5 E/M coding, so the very narrative that we're relying on to paint a picture of the patient is basically just cut and paste boiler template of totally concocted review of systems and physical exam components. We now have that in the new CMS rules that have just been announced from physician fee schedule, where in conjunction with the AMA moving to a much more realistically based charting. We'll see how that goes. That's based on medical decision-making, just as a quick snapshot.

Another burden that was -- that I think is implicated in this business of how do we communicate what

information we communicate, it's the whole quandary of quality measures. So quality measures are point estimates of provider quality and performance. Again, circa 1999, 2000, when quality measures really started coming in, that was the very best we could do technically, right, was get a curated hand-scored point estimate. You know, we had chart abstracters, various clinical coders, and we would say, oh, yeah, they did this or did they do that, and I think -- and the deputy secretary has an effort, which I think actually part of it's going on this afternoon, and certainly this week and over the month as part of an executive order from the White House on transparency to rethink what we are doing there.

Obviously, over time we think this is going to move to a big data world, right? So instead, doing the APIs and interoperability, instead of these highly curated, highly expensive point estimates, we're going to look at the totality of performance data, which payers have a right to, under treatment payment operations, and do that with any machine learning algorithm, pick your choice.

They're probably going to have relatively similar performance. They're going to be far more -- that we reproducible in scoring providers and identifying best practices. So I think, again, that's another subset of

this disconnect between financial and clinical data that we've sort of worked through in a historical.

The third one obviously is prior auth, where we just have this as Alix has nicely pointed out, this deep disconnect. To Bill's point, I think what we are really looking for here -- so when you look at decision support over the years, and a number of us have been there for the whole journey of decision support, initially it was handcrafted decision trees, and it was literally paper. It was just here's a memo, do this, do that. I remember being a med student with John Eisenberg, the late great John Eisenberg, on this in the mid-1970s in the very early days. Don't repeat the LFTs every day, kind of thing. Then we went to folks like Clem McDonald, the early rule-based expert systems, Ted Shortliffe, where we had if/then rules.

I think what we're looking for today when we look at decision support, because prior auth ultimately is a decision support problem, right? That's what we're trying to solve here computationally is a decision support problem. It's not a paper shuffling problem. It's not a document discovery problem. We have addressed it with document discovery and things, but if you look at what's the endpoint that we're looking for on prior auth, it is automated decision support.

So what we're looking for is an end-to-end that we take a bolus of data, a set of data on a patient, potentially a very rich of data, USCDI and more, and then put it to some potentially very complicated algorithm, which is either publicly available or could even potentially be a proprietary black box type of algorithm.

So we have to figure out is our policy between NCVHS and ONC and the national standards group and everybody else, we have to figure out how do we get a bolus of clinical data with a bolus of algorithmic data and do that in an automated fashion that is part of the workflow, rather than doing bits and pieces over time and doing them manually. I think that is the task there.

We're going to hear, we have a great, great panel coming up. I would say that I would have the caution, as Rich mentioned; there are a number of folks doing various intermediary things here, you know, automated document discovery, but I think to Bill's point we need to think what's the end goal of a seamless end-to-end connection here in getting clinical data to the algorithm and the decision and doing that in real time, in workflow, as opposed to manually not real time, in sort of some ad hoc expensive random process.

Those are the things. I think there are a couple good technologies that we can think about here. First of

all, the speed of adoption of FHIR has been pretty amazing to me when you think about what I've seen over the 35 or however long years I've been in this space. I think we now finally, to Rich's point, have a technology that we could sort of merge with some of the financial things. I think we have to think about how we put together the various X12 things that we have a vast national investment on from WEDI, how we put these things together with the clinical information, but that is I think ultimately the task that we need to do, and then we'll have the tools to solve prior auth to a lot of these burdens and more broadly shop for value based care. So I would say that would be I think the shared belief that I think many of us have here on that.

Tom, do you want to add in anything? You have been plowing the trenches here on things on things.

MR. MASON: Sure. No, I think you've really covered it, Don, really succinctly, and talked about sort of the challenges that we have heard from the clinician community and patients in terms of the frustrations with electronic health records and what we're doing through implementing the Cures Act and the report on reducing clinician burden, prior authorization was clearly at the top of the list in terms of where we should focus our energy, and I would just add, I'm really looking forward to hearing the panelists today and updates in terms of what

they're doing to move toward solutions around this and thank them, one, for participating; many of them participated in the panel from March, but it's really I think great for us all to sort of hear what the industry needs, as you were mentioning, Rich, and how we can be supportive and just looking forward to the rest of the panel.

DR. RUCKER: Yeah, I mean, I think we have to -- I think part of the goal of the panel is obviously this is going to take time, right? The fact that the 278 transactions are only used 10 percent of the time or whatever the CAQH numbers are, you know, I think it is a somewhat complicated, somewhat involved journey. There's bifurcation of the pharmacy journey from the rest of the journey, which may or -- may be fine on many levels, but I think the opportunity of the panelists to really start thinking about what next steps can be mapped out here.

DR. STEAD: May I make one soundbite of how important this is? An example from home-based, cochlear implants, with the normal prior auth process in place, if your family lives in Knoxville, we're in Nashville, 22 weeks with five trips back and forth, with an agreement with the employer to just pay for it under a bundle without any prior auth in two days, one trip.

MR. COUSSOULE: One more thing. I think one of the things I see is a lot of the transactions historically started, and none of them were really structured to be in a real-time world. They were all basically structured either before the fact or after the fact, and timing was not an issue. We're talking about now end-to-end real-time point-of-care challenge. So it is a very different world, and if we don't think of it that way, then we'll never get there. We'll always be arguing over how to make these disconnected things work a little faster, as opposed to how do I make it work right now and all the way through. So I think it's really important to keep that in mind.

MS. GOSS: To that point, Nick, I think that we have memorialized how we did business into transactions, and didn't do ourselves a service in that.

DR. RUCKER: Yeah, I think it's a great point, that we need to take what had been totally asynchronous transactions and make them at least near real-time, which is possible. To do that, you basically have to either reengineer the whole process, and/or decompose every step, and make it electronic, and I think we need to think of this in the way that an Amazon would think about changing things, because there are huge logistic issues involved.

MS. GOSS: Are there other questions or comments?

So we are a bit ahead of schedule, which is great, because we did not have an agenda baked in, or a break baked into our agenda. I think all of our panelists are here, but what I want to do is check in with you, Bill. Can we afford like a 20- or 30-minute break? Or we just --

DR. STEAD: I think if you keep the break to like 10 minutes, you would actually be on schedule, but maybe I am misreading.

MS. GOSS: We weren't supposed to start the panel until 3:30.

DR. STEAD: Okay, you're right. I would suggest a 20-minute break then, because I think it's always better to stay earlier. So 20-minute break, and then if we need extra time --

MS. GOSS: So 3:15 we will resume with our panelists.

(Break.)

Agenda Item: Expert Panel on Prior Authorization

MS. GOSS: So we are ready to resume from our break. Thanks to everybody's participation so far. We are going to take a next step in our agenda, which is to have a panel on prior authorization. Six panelists will present in the next sort of hour and a half or so. Each panelist will have 10 to 12 minutes to deliver their remarks. Some will have slides, some will not.

We will take clarifying questions after each panelist, and then a group Q&A discussion at the end. So we would ask, just to help us get through ensuring that all panelists have time to present the materials to just keep our questions after each panelists to the clarifying questions.

I am going to, for the sake of efficiency, have each of the panelists introduce themselves. But I will kick it off with Heather McComas from the American Medical Association while I give her the remote control.

MS. MCCOMAS: Good afternoon. I am Heather McComas from the American Medical Association. Thank you so much for inviting me to be here today. It is a great honor to be here and talk to you again on this important subject of prior authorization.

I understood our marching orders to the panelists as to provide an update for what we talked about at the joint ONC NCVHS hearing in March. I am afraid my update is kind of that I don't have much of an update.

But before you yank me off my chair and send me back to Chicago, I want to say two clarifying things. So first of all, it is not because that no one is talking about this. And it is not that there is o one working hard on this issue right now. A lot of people are doing a lot of really great important work right now.

However, from our vantage point as physician membership organization, our members are not feeling anything different. They are still feeling burdens every single day of practice of this process. And I also promised you that patients very much are still feeling the burden of prior authorization every single day in terms of delays in their care.

So what I am going to do is briefly go over some of what I think are the most salient datapoints that I have share with you before, and then kind of move forward to talk about being stuck, why we are stuck, and hopefully some suggestions and thoughts about how to get us unstuck on this important issue.

So I think you all are probably aware of the physician prior authorization survey that you may conduct in December 2018 of a thousand practicing physicians. I think some of the most important data elements from the survey were those that looked at the impact on the delivery of patient care. 91 percent of our surveyed physicians indicated that prior authorization can lead to delays in medically-necessary care.

And it is not just about inconvenience. It is not just about waiting time. These delays in treatment actually impact care delivery. Three-quarters of physicians indicated that prior authorization can be

associated with treatment abandonment. Obviously that is very concerning. 91 percent of physicians said that prior authorization can lead to negative clinical outcomes.

And no matter how many times I show this slide, I still am always shocked. Over a quarter of physicians indicated that prior authorization has led to a serious adverse event for a patient in their care.

And we were very careful in this question to indicate what we meant by serious adverse event. We basically pulled examples from the FDA definition, things like death, hospitalization, permanent bodily disability, that sort of thing. So obviously, this is impacting the health of our nation's patients. It is very concerning.

Beyond just the human impact, though, this is certainly adding to administrative ways in our health care system. 88 percent of physicians report that prior authorization burdens have increased over the past five years. So this problem is getting worse over time, at least from our member's perspective.

This slide is sort of what I call a snapshot of prior authorization, the day of the life of a physician. Practices reported completing 31 prior authorizations per physician, per week. And this workload, for a single physician, consumed 14.9 hours or almost two business days of physician and staff time. I think we can all agree

there are a lot better ways that we can be using that time to direct patient care.

And then it is not surprising that over a third of practices indicated that they have hired staff to work exclusively on prior authorization. Again, we are talking about administrative costs in our health care system.

One thing that has already come up today that I am so glad to hear people talking about is the patient face of this issue. Really, I know that we all deal with a lot of techy stuff, a lot of revenue cycle transactions. But prior authorization is different because it is really a patient care issue. This is about people not getting the care they need in a timely fashion.

And do this point and to this extent, the AMA has launched a grassroots campaign called FixPriorAuth. We have been gathering both patient and physician stories, detailing the impact of this process on care delivery. And along with the stories in our patient gallery, we also have a video called Prior authorization hurts patients. It features both physicians and patients talking about how this process has impacted their care.

Patients like Linda Haller are talking about her son, Colin, who was diagnosed with metastatic melanoma in his late 20s. He was supposed to get scans every three months to check the progress of his disease. This is

following basic clinical guidelines and following disease progression.

And every single time, every three months, those scans were delayed, sometimes by up to a whole month. And she is now left to wonder if her son, who very sadly passed away, would still be alive if those scans has not been delayed. I don't think we wish that on any mother or any of us.

And to make the point that prior authorization is still very much a problem right now, I don't know how many of you saw this Philadelphia Inquirer op ed from just a couple of weeks ago. It is from October 28th. It is a patient editorial about how this patient was having recurrent angina episodes. And his doctor recommended that he have a cardiac cath.

And the procedure was denied prior authorization, which was shocking to him and his physician. His physician spent 40 minutes on the phone with the benefit manager, couldn't get approved. And then a little while later, the patient was having severe chest pains, went to the ER. Found out his left interior descending artery was 95 percent blocked. And if you don't know, that is the widow-maker artery, so that is bad news if that has happened to you.

So thankfully, he had three stents put in. He is fine now. But he also spent four days in the hospital. So first of all, this man was walking around with something that could have killed him. That is horrible in and of itself. But we think about the cost of that hospitalization, that ER visit. This did not save the health care system any money.

So given the fact that I think all of us recognize that prior authorization is such a problem, there has been a lot of industry initiatives to bring us together and come up with some common ideas of how we can improve this process. From our perspective, the release of the prior authorization and utilization management, reform principles, and January 2017 was an important landmark in this work. The AMA and 16 other organizations released this document. It has been signed on by a total of over 100 hundred patient and physician and health care organizations.

So there were five broad categories of reforms recommended in this document. And the principles were really important because they jump-started a wider discussion in the industry between providers and between health plans on what things we could agree upon in order to improve and reform this process.

And so that work culminated in January 2018 almost two years ago with the release of the consensus statement on improving the prior authorization process. This represented an agreement between the provider and the health plan community on things we could do that we agreed upon that could improve the prior authorization process.

Things like selectively applying these requirements just to outlier physicians and to other health care professionals. To review and adjust lists of prior authorization, lists of services that require prior authorization, to improve transparency and communication and prior authorization requirements, to improve continuity of care. And also to improve the automation of the process to address transparency and efficiency issues.

So I guess we are here today to talk about where are we? What is the status of all this? And I am afraid, my friends, to let you know that our mascot for prior authorization reform is Sluggy. And he is not cute. We can do better than this.

In our physician prior authorization survey, we did include some questions about the reforms outlined in the consensus statement. We asked physicians, are you seeing these changes being made? And overwhelmingly, the response was not. I will just pick out a couple of these to point out.

85 percent of physicians are still reporting that prior authorization can interfere with continuity of care. Almost 70 percent said that they have problems figuring out what drugs and services require prior authorization. And then that bottom bullet, which gets at automation which is, I know, the sweet spot of many of you in the room today, this is still a very manual process.

Most physicians report they are still using facts and phone to complete prior authorization. So for all of our talk about electronic prior auth, physicians really are just not feeling it out there in their day-to-day practice. And only a little over 21 percent indicates they have access to electronic prior authorization for prescription drugs, which is something I think we think is further along than it is. But even that technology is not widely adopted yet.

So I know that we have already gotten into this a little bit, so let's just kind of level set here. So we have this HIPAA-mandated transaction for electronic prior auth for medical services, the X12 278. Mandated by HIPAA, but I am sure that April is probably going to mention this, too. The latest CAQH index showed that industry adopted just 12 percent.

Let's put that into context. The adoption of the electronic claim is 96 percent. So it is not like all

electronic transactions are not being used. It is this one that clearly has some kind of problem.

I think a lot of folks would agree with me, hopefully most of you, that one of the main issues is that this transaction is administrative. It does not carry a whole lot of sexy, robust clinical data. It carries some, but not usually enough for the health plan to make a decision.

So the problem is that we need a standard way to communicate supporting clinical data, right. So HIPAA, the forefathers of HIPAA knew that way back when. They address this in the HIPAA legislation saying there needed to be a standard for attachments.

In June of 2014, before this very subcommittee, a subcommittee on the standards, NCVHS, I remembered, I was early in my position in this job. I remember a major EHR vendor representative saying that the lack of an attachment standard was having a paralyzing effect on the industry. It was keeping us stuck because no one was willing to invest in an attachment standard or automating clinical data exchange unless there was a standard.

And there was a mention of attachment role in the 2018 regulatory agenda. I am not seeing a rollout yet. I don't know if anyone has seen it. But you know what? The thing is, I don't want to be throwing stones on that

because I have got to say if it were my job to release the rule, I would be a little confused.

I am going to say that I think this is a confusing time. If our little niche of the industry here today was a Facebook page, our status would be it is complicated. There are a lot of valid questions right now. There is all this activity on FHIR and DaVinci. It is exciting work and it has a lot of potential.

But I don't think any of us are really quite sure how this is all going to land and how do we get from A to B, right? Is the X12 278 transaction still the right choice for prior authorization for medical services? Do the 278 and FHIR work together to use them together, and how would that work? And if we do use them together, would that cause practices more to have to use both standards?

What implications does FHIR have for an attachment role and an attachment standard? And do we need a new mandate? I am not going to sit here and pretend today that I have the answers. And do you know what the thing is? It is okay to not know. I am telling myself it is okay to not know. And maybe some of you agree. Maybe some of you don't know, too. And it is okay not to know, but it is not okay to not have a plan to figure it out is what I want to say to you today.

We need to figure out a way to figure this out. And if it is about piloting, I know we have been doing a lot of talking about testing and piloting today. If it is about really getting a formal process of inquiry going, I think it is the way to do it. I think one possible model that kind of came to mind was way back, there was an e-prescribing pilot, the Agency for Healthcare, Research and Quality did.

And part of that was looking at pharmacy electronic prior auth. And the result of that inquiry was that the pharmacy prescription drug industry said that X12 278 does not work for us. And eventually, that got NCPDP to create the new EPA transaction. That became the standard for that niche of the industry.

Do we need something like that? I think we need that level of thing. We need a big, thick report. We need pilots. We need this to be formally studied. And then we make a decision and a path forward. And all this needs timelines behind it, right?

This is worth the investment. It sounds like a lot of work. It is, but we need to do it. And I guess one thing that I really want to say to you. I don't want to be sitting here five years from now saying the same thing. Like look, I take it as partly a professional failure that we are stuck here doing the same thing. I feel badly about

it. But it is not about me. It is about six years' worth of patients that have had their care delayed since we have been stuck like this. It is just not fair to any of them.

And a couple of thoughts here as we move forward and we keep talking about this here today. I think we all need to recognize and look at the opportunities here. This is not going to be easy. There are hard questions that need to be addressed. Look, there are a lot of prior authorization out there right now. And if we are going to automate it, that is going to be a lot of development work.

If we have so many services that require prior auth to build that out, all those criteria that are different across all different health plans, that is a lot of programming work. I would suggest that that would be a good reason to selectively apply it and be more careful about what services we subject to prior authorization because it is going to take a lot of work and dollars to automate all of this if we keep the volume as high as it is right now.

We also need to recognize that the process is really, really manual right now. And some of the discussions during CORE's operating rule deliberation on the prior auth rule that they have underway right now, there were major national health plans that said that they got an electronic 278 request.

And when they got that request, they needed a person to look at it, to say whether or not prior auth was needed and what additional documentation was needed. Just to make those two things. So obviously, there is a lot of work that needs to be done to automate the process here.

Also, this has been mentioned, too, there is a huge lack of standardization between health plans right now. They all use different criteria and require different data elements. Again, that is going to be a heavy lift. That is going to be a lot of investment and programming.

And finally, we all need to realize that if things like Da Vinci are going to work, there is going to have to be increased transparency and health plans, PA criteria, for those to be exposed to physicians and their EHRs.

And the final thing I like to say, because I always have to say this, is that automation is great. WE all love automation. But it is not a full answer. This gentleman in this article would not have been helped by electronic prior authorization. His prior auth would have been denied. He still would have ended up in the ER with chest pain and three stents.

I think that we need to again hopefully take a holistic approach to this, do the automation work, but also keep in the back of our heads that there are other policy

issues that are really important here, too. Thanks so much.

MS. GOSS: Thank you, Heather. Any clarifying questions before we go to our next presenter? Okay, Kate, you are up.

MS. BERRY: Hi, everybody. Kate Berry with America's Health Insurance plans. Thanks so much for having me back to provide some updates.

First, I want to say I agree with Heather. This is very complicated. Making it better is very complicated. And it is a lot of work. It is going to take multi-stakeholder collaborations. I just want to start there with I agree with Heather.

So thanks again for having me back. I am going to provide some updates on three key areas. One is to share some preliminary survey results from a survey that we fielded with health insurance plans just this fall. It is the first time we have done that. We are still kind of compiling the results. But I want to share some preliminary results.

I also want to provide an update. Last time I talked about a prior authorization automation demonstration project that we have been working on for quite some time and share sort of the update on that project where we are and the next steps there.

And then finally, I would like to also talk about a project that we have planned for next year that is focused on sort of claims analysis to identify outlier practices and bring those into standard practice, if you will, or evidence-based care. So those are the three primary updates I would like to share.

So starting with the survey results, and I do also want to mention those three sort of key updates, the work we have been doing since last spring. We actually have organized that work around the themes of the consensus statement that Heather referenced where organizations came together and said here are some areas to improve. That is where we have been focusing our key efforts here.

So as I mentioned, we fielded a survey in the fall. It was a pretty comprehensive survey. We sent it to both AHIP members and non-AHIP members, so all the health insurers received the survey. And we really focused on commercial business and Medicaid-managed care, primarily because based on our development of the survey which we did with some advice from outside experts and some of our members, basically said the Medicare Advantage prior authorization process isn't really any different. So we focused the survey on plans that served the commercial market and the Medicaid-managed care market.

We have had a pretty good response so far. So what I am going to share is sort of as of November 1. And we have had 60 responses, so that is roughly 45 percent response rate. The respondents cover over 100 million lives. It is a pretty good response rate.

I want to mention, so just a couple of key statistics I will share. First of all, all of the plans that responded use multiple sources of evidence, guidelines and standards to inform development of their prior authorization program. So specifically, peer-reviewed evidence studies, 95 percent, federal studies or guidelines, like CDC or CMS, 93 percent. And then plans internal data on use of procedures and drugs, 88 percent.

Also, I want to mention that all the plans, 10-percent of the respondents, as part of that process, they do get input from providers and provider organizations in multiple different ways to inform and developing the list, if you will, of what drugs and procedures are subject to prior authorization.

I also wanted to mention that we asked what are the most common types of procedures that are subject to prior authorization. And so the top services and drugs that are subject to prior authorization related to specialty care. So specialty drugs, for example, genetic

testing, high-tech imaging and durable medical equipment. Those are sort of the top areas where prior auth is used.

On the converse, if you will, very little use of prior authorization in the primary care environment. That is sort of the lowest clinical area where prior auth is used. The vast majority of plans use prior auth sparingly, believe it or not, with 84 percent of plans saying that they apply prior auth to less than a quarter of the drugs or procedures. So it is definitely a small subset as opposed to all types of procedures.

In terms of streamlining prior authorization, the types of initiatives that plans are doing include some electronic prior authorizations. Now, that may include a payer portal, which I realize is not ideal. But it also includes going through intermediaries as well.

So 80 percent say they are either moving toward electronic. 45 percent of the respondents are waiving or reducing prior authorization or step therapy for certain patients to promote continuity of care. 10 percent of plans are selectively waiving or reducing prior authorization for providing that meet certain performance standards and adhere to evidence-based medicine. So there is some selective application of prior authorization for high-performing practices and hospitals. That is in the

drug space. Pretty similar on the medical services side, too, in terms of those key factors.

All of the plans do review the list of drugs and procedures that are subject to prior authorization at least annually. About a quarter of them do it twice a year. So all the plans review those lists annually.

Some of the challenges that were highlighted, and again, these are just preliminary results. Most of the respondents, so over 50 percent, they would say that prior authorization is increasing on drugs specifically. Many fewer, so more like 20 percent, say that the prior authorizations for other medical surgical procedures is increasing.

I think the pain is mostly with the drugs. At least that is what we heard in this survey. And really the reason for that, we asked why, why are the trends going in that direction. And the rising cost of drugs, the proliferation of higher cost drugs, is really why prior auth is increasing on the drug side. Those are the key survey results I was going to share. More to come on that later as we complete the analysis.

The second area I want to update everyone on is our prior auth automation demonstration project. So we have been working on this for almost a year, actually sort of doing intelligence gathering for longer than that. And

really what we are trying to do is test some different approaches of automating. And I will describe specifically what the functionality is and who the players are. I didn't do that last time, so I want to share more.

So we are really looking at two different types of functionality that we are going to be demonstrating. One is in the prescription medication space and one is in kind of the all other space. So inpatient and outpatient, medical surgical procedures. So kind of those two separate use cases, if you will.

We are driven by the goals of using standard-based approaches that can be scalable, that are player agnostic and that are as integrated as possible with physician workflow. So that have been our guiding principles. And we are hoping, we expect, that the outcomes of this will inform future adoption, recognizing that adoption of technologies, it never happens without bumps in the road.

I happen to have been there at the beginning of electronic prescribing. It took quite some time, a decade at least, to go from 1 percent of adoption to the tipping point. I think we have to bear that in mind. And I have a healthy appreciation for that. So we are hoping that this project will inform future use of the technology that could be more successful.

So we have seven health plans that are committed to participate in this demonstration project, both national plans and regional plans. And we have, as I mentioned, two different use cases. So one of the projects is with Surescripts on the prescription medication side. And the other project with the medical surgical inpatient/outpatient is Availity. So both of those are sort of neutral gateways that enable the connectivity among payers, providers, technology support, et cetera.

And we have engaged RTI as our independent evaluator who will work with us to define the study design and the data collection plan and to produce a report at the end that will help us all understand through implementing these functionalities and evaluating the impact. What is the impact on patients? What is the impact on providers? And what is the impact on plans, so we can understand, okay, how does this work and how can we deploy these technologies in a way that is successful?

So the functionality on the prescription medication side enables essentially through the provider's electronic health record the ability when they are with the patient, prescribing the medication, real-time pharmacy benefits would be available that would tell the provider, does this drug require prior auth, yes or no? If yes, the doctor can be informed of clinically equivalent

alternatives that do not require prior auth, so just to bypass the process completely.

If the prescription does require prior authorization, it generates a form that the provider can answer the questions and submit electronically as part of that process. Plus, the doctor has access to the patients out of pocket costs real-time, so the patient doesn't end up being surprised when they get to the pharmacy, what the financial impact is going to be. So that is essentially the prescription process that we will be testing and looking at the impact there.

The inpatient and outpatient procedures is through a multi-payer portal that basically, for any other type of procedure, not drugs, the information can be provided through the portal specifically about the procedure that is being ordered. Does it require prior authorization, yes or no? If yes, the provider can submit, answer the questions through the portal also and do real-time messaging with the plan if needed to answer questions. And this is through AIP. So that is essentially that process, plus there is a dashboard to manage the entire sort of collection of prior authorization requests.

Finally, I do just want to mention, as I said, RTI is working with us right now on the study design and the data collection plan. And then we will be launching

the project in 2020. It will run for about six months. By the end of next year, we will have a report produced.

Finally, I just want to share, too, that next year, we are planning to do a project with the Johns Hopkins team that would be focused on sort of procedure by procedure, looking at claims analysis to identify sort of what is the range of practice that should be happening, who are the outliers and where are they, and to have a collaborative process to bring those outliers to improve the performance there. So another way of tackling this in terms of promoting evidence-based care, but doing this in a very different way than focusing on prior authorization. So really collaborating to bring outliers into best practice. Thank you.

MS. GOSS: Thank you, Kate. We are going to move onto April.

MS. TODD: I am April Todd. I lead CAQH CORE. We are a non-profit, multi-stakeholder organization with participating organizations that span health plans, providers, vendors, government entities, participate, as well as a whole host of standards development organizations, as well WEDI.

Our role really that we serve as, as a facilitator, to try to put business rules around to help with the adoption of standards and interoperability. We

have created operating rules for all of the HIPAA transactions to date, except for attachments, and are in the process actually of updating many of those operating rules to account for value-based payment.

And when I talk about operating rules, what I mean by that is that we are putting business rules around how to use data content, some infrastructure-related rules that may have to do with availability of systems, timeframe of response, as well as rules of connectivity.

I am going to spend a little bit of time around that today because we do have connectivity rules that have been adopted for mandate that do provide some safe harbor rules around how some of the X12 payloads are communicated between plans and providers, where we think there may be some opportunity to use some of that to help advance some of the efforts around prior authorization.

So often, we do a number of surveys. We do a number of polling activities with our participants. And over time, have really identified a number of barriers that exist related to prior authorization, which I want to highlight these first before I go over a number of activities that we have been working on with our participating organizations, as well as some that are coming up.

So in terms of some of the top barriers that we have identified, one of the main ones is the need for consistent use of data content. I think we have heard about a lack of use of the 278. From what we have heard from people is that there is a lack of standardization of how to use the 278. And so that is one of the reasons that it is not used.

Another reason that it is not used, and I will hammer on one of the points that Heather had made, as well, is the lack of an attachment standard for communication of clinical documentation. We hear repeatedly from everyone. And how we refer to it really is it is communication of medical documentation and how we communicate that. That is really what is impeding that use.

Also a general lack of integration between clinical and demonstrative systems. That is creating a lot of angst in this space. Next is the limited availability of vendor products that support prior auth. As we have heard, there are a number of portals that plans have developed to help with some streamlining of this. But there really are very few vendor products that support prior authorization.

Other barriers that we have heard as well is that there are various state requirements for manual intervention. There are various state requirements that

plans and providers are subject to related to prior auth. That lack of standardization has also created some issues.

We also hear about a lack of understanding about what the 278 can do. And even then, it is the mandated transaction. A large percentage of providers, a large number of providers do not know that the 278 is required. They do not know that there is a way, that if they request to use the 278 with a health plan, that they have to support it. Providers are not generally aware of this. And so there is a need for education and communication on that point.

And then lastly, there are just varying levels of maturity in the technology spectrum across plans and providers from those that are very large that are doing and experimenting with things like FHIR that is great. There are those that are much smaller that are not anywhere near being able to do that. I think those are a lot of the barriers that we encounter in the work that we do.

So based on those barriers, we have set up a pathway to try to work on as much as we can as CAQH CORE a way to address as many of these barriers as we can and do this as quickly as we can. So I will talk through each of these five, and we have a number of things that are going on here. I will try to talk about it at a very high level.

Can go into more depth in more questions later, but there is a lot of material here that I would like to share.

First is around data content. We have a phase-five rule for prior auth that does standardize some of the data content and how that can be used for the 278. We will talk about that. That data content should help speed up the timeframes with which plans and providers can communicate information related to prior auth.

So that has led to us having the capability of working with stakeholders at the moment on rules related to timeframes for responding with information on what documentation is needed and a final determination from a plan to a provider on a response to a prior authorization. That is in the works. We will talk a little bit about that.

I do want to talk a bit about some opportunities for updating our connectivity rules from those that have already been adopted and potentially some opportunities that exist there to make some connection between administrative and clinical transactions, and try to bring in some new technology capability. We are also in the process of doing some surveying and some advisory groups related to communication of medical documentation.

We are trying to get ahead of a potential standard being announced related to attachments and working

on those operating rules. And then lastly, we are engaged in a variety of pilot discussions to start to measure and test the impact of some of the operating rules, and also identify areas where we may need operating rules to help smooth that end-to-end transition.

So in terms of the first area that I mentioned, which is around data content, we do have phase five operating rules that were passed by our board in May of this year. And they include a few specific things that I think are important.

And specifies data content requirements for patient identification, error and action codes, communication with providers about needed information and clinical documentation. So exchange of different link codes to communicate that, to help providers understand what the status is of the next steps.

So creating some standardization around what information should be exchanged and how that should occur. So this should reduce some of the manual back and forth that occurs between plans and providers, hopefully eliminating some of the need to pick up the phone and ask for more detail. And help to encourage some of that auto adjudication. We still do not have automation for how you communicate clinical documentation. That is still a

barrier, but this is a significant first step to help move along that path.

And then secondly, as Heather alluded to earlier, we are currently in the process. We are in the middle of our voting process. We are at our all participant CORE vote on a set of rules related to timeframe for a response to a prior authorization.

So what is currently out for a vote right now with our participating organizations is that there would be a two business day maximum timeframe for when a provider submits a request to a health plan for the health plan to respond back with this is the documentation this is needed in order to complete the prior authorization request.

And once the health plan has received all the information that they request for that prior authorization, that there is a two business day maximum timeframe for when the health plan can respond back to the provider with a final determination on that request. And I should specify as well that this is for non-emergent, non-urgent prior authorizations. This is your typical standard prior authorization that this would apply to.

We do anticipate, assuming that this rules passes through our timeframes for our voting process, and how that typically works, we would anticipate bringing the updated rule set on timeframes, as well as the data content in

phase 5 to NCVHS for review, either make that request in December of this year or January of next year.

So in terms of connectivity, we have a white paper that will be coming out shortly where we have been talking about some activity we anticipate engaging with our participating organizations next year to start to update different components of our connectivity rule. What you will see on the left-hand side there around transport security, authentication, message interactions, APIs and web services, all of those things are specified in the phase 2 connectivity rule today. It references SOAP, it references of a different TLS standard for that. We are planning to discuss with our participating organizations next year updates to the standard that could potentially start to include safe harbors for rest and APIs.

Related to attachments, we have an advisory group that is currently in process of helping to identify priority areas should a standard be developed of things that we will need to be specified in operating files. So we are working on that.

But as we are working on that, we sent out a survey earlier this fall. It actually just closed as of November 1st. So these are very early preliminary results from the survey. There will be more to come. But the survey that we did on medical documentation is much broader

that prior authorization. We are trying to look at this much more broadly. It includes prior authorization, it takes value-based payment, claims and quality measures. So we want to really look at the full breadth of what clinical documentation could be used for.

And what we did in the survey is we asked our participating organizations to share with us how they are communicating this information today. And what is the distribution by specialty of the need for exchanging medical documentation. And specifically, we have asked some detailed question around the use of the CDA, and what might be missing from that, that could be communicated?

So again, these are very initial results. We have 340 total responses to this, a very good mix. We are very help to get a lot of provider organizations responding to the survey on this. What we have found some of this is not all that surprisingly to you is mail/phone/fax, by and large, this is the vast majority of the medical documentation is continuing to be transmitted this way. However, we are seeing a fairly sizeable percentage of documentation being communicated through portal upload and secure e-mail. That is going through the use of EDI and FHIR is extremely rare. It is very rare that we have received anyone using those mechanisms.

In terms of the initial results to one of the questions, I promise more of the results will be coming out soon. But what we have asked both providers and health plans was, of all the medical documentation that you exchange for prior authorization and for claims and value-based payment, what is the distribution of that by specialty? What are you most needing to exchange medical documentation for?

And what you will see here is some similarities and differences that we are getting back between providers and health plans. For providers, you are seeing very high need to exchange medical documentation for prior authorization related to radiology, hospitalization, behavioral health, cardiovascular neurology, health plans.

Some similar information there. Hospitalizations, orthopedics, post-acute oncology neurology are the distributions that are there. And what we have done with the survey results is weight them to be representative of the size of plans that are in the market, as well as size and characteristics of providers as well.

I already mentioned this. We are working with our attachments advisory group to come up with some needs for operating rules. I won't go into all of these in depth. But just to give you a flavor for some of what they might look like. One of them is the need to, for example,

associate medical documentation with the actual prior authorization requests.

Then the last thing that I will mention here is that we are doing a number of pilots. We are in discussion to monitor a test, operating rules and ROI for pilots to just identify both what are some additional operating rules that might be needed, as well as start to test those that we have recently passed and the impact of that.

So we are starting to work with our organizations to do that. I am definitely not going to go into this in level detail. But I did want to share this because this has been helpful for I think the industry to understand end to end, the path of prior authorization and where are there opportunities for clogs and opportunities for options for how information can be exchanged. And these are the different points along the path where we are trying to test and trying to evaluate how we can help prior authorization better.

So with your reading glasses later, I just wanted to share this for reference. I know we want to close up here, coming at the end of my time. This is our roadmap for what we are working on, on these five areas. We are trying to move as quickly as we can in engaging with our participants. Agree with everyone in this room the need to try to resolve this. And so we are trying to do what we

can around operating rules to use the levers that we can to help to improve this.

MS. GOSS: I apologize for not indicating that Loraine will be helping us maintain or manage our timing today. You picked up on the cues. Thank you for doing that.

While we are pivoting, after Mary's presentation, we are going to have Jay and then Pam. If we could have some switching out at the end of the table to accommodate, that would be fabulous. Mary, it is all yours.

DR. GREENE: Thank you very much. I am Mary Greene. I am a senior advisor in the Office of the Administrator at CMS. I am a pediatrician by training. I have been leading CMS' Patients Over Paperwork initiative, which is a burden of reduction initiative. That is the lens I am bringing to the table today, and that is burden reduction in some of the work we are doing through Patients Over Paperwork.

I do want to thank the committee for inviting CMS here today and also ONC inviting us. I just want you to know that the administrator, Verma, recognizes how important prior authorization is, solving the problem of the current state of prior authorization. And she has made it a top priority for the Patients Over Paperwork initiative this year.

And also, we have some folks on the phone who are listening intently to get some more insights from you and get a sense of where you think the path forward is.

There are three messages that I want you to take away from these remarks. One is that prior authorization needs to be effective and efficient for the sake of our beneficiaries. I think the beneficiary angle here has been coming out in each one of the conversations. It is incredibly important that we keep our eye on the ball of what we are actually trying to achieve.

The second is fixing prior authorization requires more than technical solutions. There are non-technical issues that need to be addressed as well. In some ways, the technical solutions are getting a little ahead of the non-technical, and in other ways, it is the other way around.

And then the last one is CMS wears various hats as it works with the medical community to make prior authorization exceptional. And first, I will just say you probably haven't heard the words, prior authorization and exceptional, in the same sentence. Why not? Let's just make that happen.

Sometimes, the different hats we wear causes a little bit of confusion. I just want to address that, as well. So the first one, prior authorization needs to be

efficient and effective for the sake of beneficiaries. And this is the way we think of the challenge that we are trying to address.

That in the context of prior authorization, we want to ensure eligible beneficiaries get medically-necessary items and services in a timely fashion with minimum demonstrative burden. And that is not just for the beneficiaries. It is not just for the clinicians. It is for any stakeholder that has to touch the process in some way.

Everybody has been essentially saying this actually in their comments today. So the beneficiary gets what they need because they really need it. They get it timely, and it is with minimal administrative burden. And that should be true no matter what the item or services is getting prior auth. Whether it is a medication or a biologic or a diagnostic test, anything at all. And it should be true as well, even when a beneficiary moves from one health plan to another. That transition shouldn't lead to huge gaps in a beneficiary's care. Somehow, we need to safeguard that during those transitions.

There is no question at all that prior authorization is important for utilization management and for supporting evidence-based care. And the one thing that you will heard the administrator over and over again, it is

not something that is going to go away unless all the data that Don is talking about will give us completely different ways to be able to monitor for that sort of thing. I think we should all be hopeful on that.

But it is not going to go away. But if it is onerous to go through the process of prior authorization, that is a problem. And it is not just a problem of inconvenience for the people involved.

And you heard from Heather and others already, that there are real challenges in terms of patients paying more out of their pocket because they don't want to wait for prior authorization. Or they completely abandon their care. And then we have heard that there is some indication that prior authorization might be associated with adverse outcomes. And presumably, it has delays in prior authorizations or maybe decisions that weren't made quite right.

Bottom line is we have been talking for a couple of years in Patients Over Paperwork about electronic health records being the greatest source of clinician burden. It is really the source of clinician burnout. When we heard about six months about that it is actually prior authorization that is the worst thing, that absolutely got the administrator's attention and it got everybody's attention. Frankly, she is having us take a look at prior

authorization across all our programs, Medicare, Medicaid, including even the marketplace. It has really risen to the top as I mentioned a couple of times.

So this past summer, she charged us specifically with looking at the process for prior authorization. So getting prior authorization, navigating appeals, the timelines involved. She deliberately asked us to stay clear right now of the substance and content of prior authorization. The basis of prior authorization decisions, what clinical guidelines are actually being used. There is a lot of variation there in the medical community. But most importantly, the process itself is the most immediate thing. There is a lot more complexity around the substance and the content at this point.

So over a six-week time period, we went out and asked people again about prior authorization specifically. We engaged well over 300 people, clinicians, providers, plans, beneficiaries and technology companies to participate in interviews and 29 listening sessions. We talked to CMS SMEs as well.

We captured input on prioritization through the lens of burn reduction, but also the lens of quality and safety for the patients themselves. And as part of this process, we even set up a center director executive steering committee to guide this work. This was to make

sure they were aware of the work. They were aware of what we were learning.

But to also make sure that every single center was thinking about every single program they had that touched prior authorization, and see what we can learn from one another. And most importantly, whether there could be some better alignment across the programs. This yielded about 2300 datapoints that we are still in the process of analyzing.

There are 96 issues that were put on the table. And some of them, as you hear them, they are amenable to technical solutions. But some of them as plainly business decisions that people need to make a real prior authorization. So that is the beneficiary.

Now, fixing prior auth requires more than technical solutions. So here are examples of some themes. This is all going to sound familiar to you at this point given the conversations so far.

So better access to information for beneficiaries and clinicians. That includes the beneficiaries even understanding what their benefits are or what the clinicians getting access to what is really covered for that beneficiary and what is not. What needs prior authorization? What clinical information needs to be provided to get prior authorization?

And remember, that is a set of rules. We have our set of rules. But each plan has its own set of rules. So when a clinician tries to figure this out, soup to nuts, for a plan, it is just one plan. And oh by the way, a payer can have multiple programs. And prior authorization, even for the same health plan, could have a variation across the programs they put in place partly because the requirements of the payers that they are providing the services for.

So remember that it is a multiplier effect. If you have a family practice that is dealing with 6, 8, 10 plans, even more, it takes a tremendous amount of their time just to work through prior authorization, let alone all the other administrative requirements they may have for their practice.

Communicating the prior authorization decisions, we talked about that a bit already. Communicating the reasons for denial and the need for additional information as well. Those are examples of things that people tend, as they talk to us, put in the bucket of there are technical solutions that can help with that.

But there are also issues like what rally is the clinical basis for the prior authorization decision, and why are certain practice guidelines used and other practice guidelines are not used. And why do different plans use

different practice guidelines? And clinicians even tell you that different medical communities will have slightly different practice guidelines before seemingly the same things that they are trying to treat.

Technology is not directly going to help that. Maybe big data over time is going to help clarify what some of those decisions really should be ultimately. But right now, those are business decisions that are being made, and whether or not to have that variation are business decisions, as well.

Beneficiaries understanding and being aware of prior authorization. Many beneficiaries don't know anything about it until they find they suddenly need prior authorization. They don't know how it works. They don't understand why they think the clinicians getting in the way of them getting what they need done. It is the process that is really getting in the way. It needs to be more efficient.

Grappling with peer-to-peer review, so a clinician has to get on the phone and talk to another clinician about exactly what is going on and what is unique to this particular patient to get a prior authorization decision done. Many clinicians feel like they can't talk to a clinician who is actually well-versed in that particular clinical area.

I want to just mention the word, standardization here. There are a number of people who come to us and say, please standardize this aspect of prior authorization, that aspect of prior authorization. And they are all talking about different things. So when folks come into the room and they say we agree that we should standardize prior authorization, sometimes they are talking about the data elements. Sometimes they are talking about how the transactions work. Very often, they are actually talking about the content, but you have to ask them about that specifically.

The last thing, and I know I am being told to wind this up here, I do want to just mention the three hats that CMS wears when we deal with this. One is you have already talked quite a bit about the divisions of national standards. And on behalf of HHS, they are responsible for implementing and enforcing the administrative simplification provisions in HIPAA and in ACA for electronic transactions codes, the identifiers and operating rules.

And there are certain rules that they have to follow to get to those approvals. And you expressed today how much you admire how long it takes for them to actually thoroughly get through it. It is a challenge, and some of it is what they are actually required to do. I want you to

realize that is a responsibility, and enforcing those rules is their responsibility to do.

CMS as a payer is responsible for following those mandated standards. We are supposed to implement those mandated standards. But CMS is also responsible just generally for innovating and for fostering innovation in the health system. That is why you will see us innovating and working with people who are working with emerging standards, as well, like the FHIR standards for example or other emerging standards.

Participating in learning about them, first of all, and potentially participating on some pilots to understand them better and see what might be promising. Those three hats are worn by different people within CMS . And sometimes it is confusing for folks. They ask why is one side saying this and one side saying that. It is their responsibility. If you are not sure what hat they are wearing, just ask. We have become more and more conscious of that and plan to communicate that a little bit better as well.

So three things, prior authorization needs to be efficient and effective for the sake of our beneficiaries. That has got to be our target. Our target is not getting the standards in place. It is to benefit the beneficiaries.

The other is that we need more than just technical solutions. There are non-technical issues that we have to deal with. And the last one is remember, we are wearing three different hats, in earnest, trying to do all three of them and help us when we are not clear on that.

MS. GOSS: Thank you very much. We are now going to move onto Jay. If you want to go ahead ad introduce yourself, that would be great.

MR. ESENSTOCK: I am Jay Eisenstock. I am the board chair of WEDI. We appreciate the opportunity to be here today to talk with the committee. We, as a multi-stakeholder organization made up of payers, providers, the vendors that support them, state and federal agencies, SDOs, pretty much everybody across the industry.

Over the course of our lifetime, we have performed many surveys with our membership on various topics, things such as ICD-10, health plan ID. And most recently, we did a small survey on prior authorization, which I want to share with you today.

So we had about 127 respondents made up of providers, payers and vendors predominantly. And I am going to come back to this later as I go through some of the slides. But what is interesting to me is the providers that responded were actually practicing physicians or those in practices. And I think it gives a little bit of a

different twist on some of the things we said, although I will tell you ahead of time, a spoiler alert, I guess, is that the results that we saw is similar to what has already been reported today.

One area here is in terms of the perception of prior auth. Providers note that there was increase, and payers predominantly didn't think that there was. They kind of thought it was steady state.

Again, something that we have been talking about here today. Payers report that their websites, portals, bulletins and so on are leading methods. Providers view portals and websites as the most common method for them to do prior authorization. Telephone was not a selection, but providers did indicate that telephone was a common method as well.

There is definitely a mixed ability for provider organizations to determine if a PA is required. Again, I think we have heard that with some of the other speakers here today. There is not the capability within their systems to get that information easily. They have to go externally in order to get that data.

A relatively small number of payers noted they used utilization management organizations. This result frankly may be partly because we have got a lot of state Medicaid agencies that participated in. They probably

would be unlikely to use that. But I know that is something that has come up, and I think that April mentioned that in her survey, as well.

So this goes back to the challenges in terms of how do you determine as a provider how to submit prior auths? And again, consistent conversation that we have been having all along. Just again, it is another way of looking to see that the fax portal phone tends to be the most significant version of that.

And this one was a little bit interesting because in this slide, the information that we got here, providers and payers were really not in sync necessarily about how all these requests are initiated. The providers viewed portals and phone and fax as a way that they typically respond to requests, and the portals and more electronic means were more prevalent. They are a little bit out of sync there.

And similarly here in terms of the response to the initial request, the portals continue to be, I think, the area that are used the most by both. This is a busy slide. But data on final determination from a previously pended response, as you can see here again, we are kind of all over the place.

I want to make a note here. It appeared that most of the respondents that we had were not all that

familiar with the 278 transaction. And again, we don't know for sure, but part of our theory in that was the fact that again many of the respondents, especially on the provider side, were actually people using it, the provider organizations, and may not be familiar with the transactions at all because they would have no need to actually know what the transaction were. That could be clouding some of these responses as well.

And again, this goes to the same thing that the reaction to the 278 transaction was underwhelming. But again, I think that is consistent with what continue to hear in other surveys as well.

In terms of the clinical attachments, there is mixed support that we saw here. Vendors obviously are crucial to this. But they are split. About 50 percent believe that they can support it today from what we saw. And I think the lack of a standard continues to be a barrier in the use of the 278 and other means in order to automate this. That is it. Thank you.

MS. GOSS: Thank you for that update, Jay. We are now going to move on to a face that may not be familiar to everyone. We want to include Pam Dixon in this panel to help us focus on some of the privacy aspects. So I am going to have Pam introduce herself and her role in the industry and provide her comments to us.

MS. DIXON: Thank you. I am Pam Dixon. I am the founder and executive director of the World Privacy Forum. This is my second time before NCVHS. The first time was when Mark Rothstein was still chair. I was asked to testify about the potential risks in the National Health Information Network, if you remember those days.

I had too long to prepare for the testimony. And Bob Gellman knows this story. I sat down and thought about it, and I thought, well, what are the risks? I wonder if there is identity theft in health care systems?

So I coined the term, medical identity theft. And then Dr. Rothstein said, you know what? You ought to write a report about that. So we did that. Now we have medical data breach and some other good things. I hope that this testimony is as helpful at least or hopefully more.

I am going to provide some context for these issues from my point of view as a privacy expert who has done a lot of work in the health care sector. Then I am going to talk about some key risks, five of them. And then a little more focus on some solutions, some proposed solutions, to the risks. Let's dig in.

So the first thing I want to say is we are moving in general from an era of the internet as a general purpose

technology to an era of prediction. And all of you are experiencing this change profoundly in all of your systems.

So 25 years ago, the main thing that you heard about was let's digitize and everything was being digitized. We were just getting our mobile phones and whatnot. But now, pretty much a lot of the world is digitized, even the developing world is largely digitized. I actually watched India go digital. Within five years, it was just unreal.

But after the technologies, the general purpose technologies, have matured, then you really start edging into the predictive technologies. And we are really standing on the precipice of that right now. We are really going through a C change. And the health care sector is definitely going through a C change. Yes, maybe there are some little bubbles and lakes here and there that need to be digitized. But primarily, everyone is thinking about AI, the predictive technologies. I will be talking a lot about that.

So the second context is that privacy law has changed meaningfully in the past 25 years. We all know that HIPAA is out of date, but that is really not what I am talking about. I am talking about the ideas, the fundamental global ideas around what privacy means have really changed.

So at one point in time, it was really about fair information practices. And that really forms the basis of HIPAA. But now, it is something quite different. And with the advent of Europe's general data protection regulation, you really have the idea of FIPS plus.

So for example, now it is very common throughout more than 130 countries to find the right to delete. Kenya just passed a comprehensive legislation doing this, right of access, which is much broader than anything we have in the US, and certainly broader than accounting of disclosures in HIPAA.

Prohibitions on automated processing, yes, this is part of GDPR. And then of course, much greater transparency. You see this both in Europe and the folks adopting European type laws, as well as some of the state-level regulations that are coming up. Washington State is proposing a new bill. California has already passed on. There is a lot of state-level action that have these new rights involved. That is the context for the remarks I am going to make.

So let me switch and start talking about the risks. The first thing I want to say about the risks is that these are ecosystem risks. I am not going to talk just about prior authorization, although prior

authorization is certainly included. But looking at the overall ecosystem, I think, is really important.

I served on the HL7 board for quite some time and have since then still been involved in a lot of standards setting. I am working a lot with IEEE right now and then doing a lot of work with voluntary consensus standards. So my viewpoint is really from a lot of standardization. Forgive me for that.

Key risks, number one, of the risks that I see from a privacy perspective with prior authorization is this impetus to remove the burden at all costs. This does include certain costs to privacy and to patient trust. If we move to a fire hose of automation, where you have got these APIs using FHIR standards that are moving into the EHRs, I do think that there is going to be a lot of burdens associated with that.

And the trendlines now are a little bit different than doing that. Well, the fire hose approach has been used in other sectors. It was used more along the lines of 10 years ago. In the health care sector, I don't think the fire hose approach is the right approach. I do have some proposed solutions for that approach for you to think about. But just in general, I would say that you have to be really careful about thinking about the dream of a fire hose of data.

Proper implementations are going to be architecturally sound, are going to provide data minimization and just in time information. Stable interoperable architectures that can be scaled in proportionality. And an interesting thought here is that there is a lot of discussion about fragmentation in literally every sector.

Fragmentation has brought what I call privacy by obscurity. And patients are used to this. I would dare say that all of us in this room are used to this. And when it goes away, as it has in some jurisdictions like India, it is shocking. You end up with Supreme Court rulings changing the law because it is so shocking to people.

The second risk is the reduction of data minimization as a goal. So I do think this is a very risky goal. And I hear this talked about a lot in the health care sector. And I just have to say that I think that reducing data minimization, so you reduce barriers, is not an answer full stop.

I think that reducing standards for data minimization is going to prove difficult over the long term. I am going to talk about this a little bit more and the solutions as to what might be a better solution. But I do think that data minimization is a good standard. And I think it is actually helpful in a lot of ways.

We see a data immunization problem in the area of actually facial recognition and biometrics. What do you do when you get a life without data minimization? And what you are seeing in the state-level bands of biometrics is what you get when you have no data minimization.

So there are two sides of the data minimization coin. There is tension if you have too much of it, but there is a lot of tension if you have too little of it as well.

I have two points on data. I call one data risk, the infinite mirror problem. So when you start to move into an era of prediction, you really need a lot of data for that. And getting a lot of data is like you are standing in front of a mirror, and you have a mirror in your hand, and you are in a mirror, you can never have enough for AI systems. It is not possible.

And to solve a problem that you are having in AI systems, such as perhaps bias, in order to solve the bias problem, you have to go through a very intrusive data collection to solve that problem. And it keeps repeating itself in an infinite cycle. I served for two years on the OECD expert group that wrote the global guidelines on AI. We really saw this problem just in every sector and in so many different ways. It is worth avoiding.

Then I would say the interoperability problem is part B of data. I think that interoperability is a really big problem. And I believe that the health care sector is going to solve its problem, speaking from my former HL7 hat. I really do think that there has been extraordinary strides made.

But I think the risk is actually coming from outside the health care sector. We are moving into the era of prediction where you are going to need a lot of external data. When that external data comes in, it is not going to perform to health care sector standards. And I do think it is a risk that is worth thinking about and preparing for.

Fourth risk is AI. There are pathologies in the data. There are pathologies in the algorithms. There are pathologies in the interpretation. There are pathologies in the use of AI. There are pathologies in how the systems are updated and how frequently. And there are pathologies in the fit of the algorithms.

Someone mentioned, actually a couple of you have mentioned, outliers. In finance, if you are an outlier, you might not get a loan or a credit card or a credit rate you want. But if you are an outlier in health care or in AI-related health care, it can have very meaningful health consequences. So I do think that AI presents unique

problems. I spent a very long time studying them and am very happy to talk with you more about them.

And then finally, the last risk I want to bring up is the problem of social traps. Bo Rothstein is a scholar who has done a lot of very important work in this area. Basically, social traps is when there are stakeholders in a sector or an ecosystem, and there is a lack of trust between them. And basically, they cut off their nose to spite their face. They won't help each other even if it is in their best interest to do so because they don't trust each other.

Now, in the health care sector, the big risk is there is a payer provider lack of trust. But we are really moving into an era where there is a patient lack of trust. And that has to be guarded most, most jealously.

And if you have been looking at the headlines the past few days, you will see that is a very real prospect when there are surprises to patients. When patients feel like they do not have control of their health care data within the health care sector, there is going to be a breach of trust. And that is very, very hard to win back.

I have eight proposed solutions for you, and I have just enough time to whip through those. It is going to be quick. So first, there is a great need for expanded oversight of third-party data uses and analysis in the AI

and scoring sectors. So as the health care sector, including in prior authorization issues, moves towards the use of AI, if you are bringing in outside vendors, or even if you have a team that you have trained within your own institutions, there is going to have to be someone or some institutional body that is created to provide oversight.

Because most health care providers do not have the skills or knowledge or background to truly look at a system and say is this fair and just AI? This is a really big deal. I do think we need some greatly expanded roles for oversight of this kind of AI activity, especially when it is being done by business associates under a BAA.

Second, there is going to have to be a reckoning between the operations of TPO and research. So right now, in the area of AI in particular, there are permeable lines between what constitutes operations and research. This is a really difficult area. If you haven't encountered it yet, you will.

So let me give you an example. So for AI, you have to have a lot of patient data to do this, a lot. It can be encrypted sometimes. Sometimes it is not. There are a variety of ways of doing this. But no matter what, you are going to be chewing up a lot of data.

How is that data going to be used? Is it truly operations? Or is that patient data being used to create,

for example, generalizable knowledge, perhaps knowledge about how to build an AI system? Perhaps it is improving an existing proprietary piece of software.

This is the question that I urge you to grapple with. Is that research or is that operations? So different people, all very intelligent, all very well meaning, have come to different conclusions about this exact question. I encourage you to think about it and also create rules around it. IRB reforms or something new? That is a big question.

Number three, a very important solution is to add governance for the role of AI in decision-making in health care. And what I mean by that is, yes, we have HIPAA. But in terms of AI decision-making, there are other guidelines and other guard rails that are incredibly important.

So for example, the Fair Credit Reporting Act style of guard rails don't really exist the same way in the health care sector. They would be very important for AI decision-making processes. There are also some additional types of fairness and just processes that are involved in AI decision-making that can be included into the health care sector, decision-making process that already exist.

And then something that also has been mentioned here today, and I was really pleased to hear it, is real-time governance. So I really do believe the world is

moving toward real-time governance systems, a lot like FINRA in the financial sector, and a lot like the Andhra Pradesh real-time governance at the state level in India.

They are extraordinary systems. I encourage you to look at them because the governance is quite complex. But it is also very efficient. It happens in real time. You have to build the system. It takes years, but once it is built, it is extraordinary.

Transparency, build new transparency mechanisms full stop. See the newer standards that exist in GDPR and the CCPA. Transparency is not a notice of privacy practices anymore. What will patients be expecting from health care providers in transparency? I propose to you that it is going to be greater expectations of transparency. It has changed. It goes back to that modern idea of privacy. And again, greater transparency reduces patient surprise at, for example, business associate activities. And this is important in AI.

And then six, the importance of bringing all the stakeholders to the standards process. I know this is difficult. I know that it is hard to find good stakeholders. But I have three words, patients, patients, patients. They have got to be involved.

Also, I really like the idea of employing smaller standard slices through voluntary consensus standards akin

to what the FDA is doing with medical device voluntary consensus standards. This invokes the OMB circular A1-19 process. It is a due process standard setting. But it is not an anti-standard setting. It is faster, it is leaner, it is meaner, but it really works.

And then two more. Number seven, develop risk scoring rules. So moving into an AI era, which all of you are going to be drug into, what are the procedures for handling risk scores of patients? When AI has been used to make an evaluation, and it is based on a patient's record, or it is used in their care, it becomes PHI. It is disclosable to the patient.

So what are your rules as a health care sector for disclosing scores from AI to patients? Do you have them yet? If you don't, it is time to make them. What were the procedures and standards used for disclosing? How will payers disclose scores? How will providers facilitate patient access to scores? How will there be an accounting of disclosures in this context?

So machine-learning really adds a lot of complexity to account of disclosures. It is really good to look at that.

I am going to close with voluntary consensus standards and voluntary consensus agreements. So as a risk analysis, and I am going to put a spin on this, as risk

analysis moves to external entities outside the health care sector, so for example, if anyone is purchasing data broker lists, if any information intermediaries are being used for white box hashing or white box analytics to do any kind of AI, this does create a new standards requirement. And you have got to make a decision about how you are going to do that. And again, I think voluntary consensus agreements and standards are really important.

What is the plan for getting patients at the table? Do you have one? What is the plan for getting privacy scholars at the table? What about the global standards that you are looking at for global health interchanges which are coming?

Are you looking at the developing world to look at what the interchanges issues are there? For example, things like the electrical grid. And finally, what does progress look like here? I would say progress looks like evidence-based privacy. Privacy is not rhetoric. Privacy is something that happens on the ground every single day and how you are doing things.

Evidence-based use of data and technology, and evidence-based decisions about the amount of data needed, that is what progress looks like. Progress looks like patients being engaged in that process and never being surprised by a data use. And seeing something in a

headline that makes them chilled from going and seeking health care.

So I think these are all goals that we can agree to. I think we can all agree that health care is an extraordinary complex ecosystem with layers upon layers of networks and ecosystems within it. And any kind of complexity like that will always be difficult to navigate. But that is part of the fun. Thank you.

MS. GOSS: Thank you. This has been a very interesting panelists remarks. There is some commonality, and there is definitely some new food for thought, especially from Pam's presentation.

I think we want to open it up for some Q&A of the panelists. I will start with anybody on the phone who may have any questions.

DR. PHILLIPS: I have a question for both Kate and for Dr. Greene. I heard you both say you are looking at low performers, people who are doing things that are low value care. Or you are looking at not maybe the individual, but across the spectrum. Are you looking at the other end? High performers, low cost physicians with high quality that you might say these folks may not need prior authorizations? Is there a threshold in the other direction where you reward their outcomes, their behaviors, and take away the burden of prior auth?

DR. GREENE: That issue has come up a lot. Some people call it gold carding. It is really based on a demonstration of following practice guidelines or proper utilization, doing right by the patients, that sort of thing. That potentially prior authorization could be reduced.

Sometimes people will say if there is a particular service that gets the prior authorizations approved 95 percent of the time, maybe that whole service doesn't need prior authorization anymore. I would say that I have heard more conversations about reducing prior authorization for specific clinicians or specific providers as opposed to the service itself.

Program integrity people will say 5 percent that are doing that, they could actually be where the real problem is. so the question is how to do it, when to do it and how often to revisit it. But I think it is definitely on the table and something that we all have to figure out how to do well.

MR. COUSSOULE: I think the studies have tended to show that the gold carding kind of reverts the mean a little bit. But there is also a question of a sentinel effect. If you are requiring something, you may not reject a lot of things because people don't ask for things they know are going to get challenged. I don't know if you have

any thoughts on that as well. I didn't mean to interrupt you. I just wanted to follow on to that.

MS. BERRY: We have been looking at kind of the selective application for prior auth for high performers in a couple of different ways. One is relating to groups that are able to take on risks and responsibilities, so that in value-based contracts where the provider group has enough size and infrastructure and experience to actually take on risk.

In those situations, plans are delegating certain functions to the provider organizations because they are taking responsibility. And so that could include prior authorization. It is really delegating the responsibility and the provider group polices themselves. So we have had some work in that area, and plans are doing that especially in risk-based contracts.

I think that the gold carding issue, I would agree. We have talked with our plans about that. I think it is a very attractive concept to providers. Our plans try it and haven't had great experience with it. There is a sentinel effect. That is a real thing.

It is really complicated in the sense that one provider may not perform well across all the services that they do. So it is complicated that way. And then there is sometimes the performance coming back. But I also think

that the plans reviewing the list all the time and looking at the data and looking at if really everybody is getting them all approved, that is why they fall off the list. There are multiple ways there.

And then on the question of looking at outliers. This is a project that we have planned for next year. We haven't done it yet. But the idea is that there is a Johns Hopkins team that has worked with CMS and some private payers on procedure-specific claims analysis and looking at kind of like the full spectrum and looking at sort of the best practice and working with outliers collaboratively to bring them in. So that is sort of like it is not even using prior auth. It is using collaborative kind of like showing the data and working through that way.

DR. PHILLIPS: Just as a follow-up, we published a couple of studies using Medicare claims data for general internists and family physicians showing that total cost of care is an imprinted behavior. You tend to practice like you were taught. That lasts for up to 15 years.

People do regress the mean, but they will regress in both directions. So the high-cost physicians landing in a low-cost area will become lower-cost physicians over time. But so will lower-costs physicians landing in a high-cost area will become higher-cost physicians. And

this idea of gold carding might prevent that regression from happening.

MR. LANDEN: April, one of your points was about state regulations requiring manual interventions. Can you describe a little bit more about what that is and possibly give examples of which states require what?

MS. TODD: There are a number of states that have, in particular, requirements for a manual response when it is going to be a denial. That there has to be a manual communication that goes back. Usually it is a mail document that needs to go back. Usually it will go back to the patient, as well as the provider. Not that an electronic couldn't also go, but there are some requirements that that be conducted.

There are also requirements that a phone call be conducted between the provider requesting and somewhat the health plan if there is the likelihood of being in denial. So in some instances, in part of the flow, there is a requirement for that manual touch.

MR. LANDEN: Thank you. It seems we have pressure on both sides to do much more automation all the way to AI. And yet, maintain a human intervention in the chain, too. So interesting industry.

I think there was a question on the phone from Frank.

DR. PASQUALE: I have two questions that are probably for Pam, but really could go to anyone on the panel. We have sometimes talked a little bit about minimum necessary and the idea that minimum necessary is getting in the way of fuller or even unfettered access to the records necessary to do either automated or other semi-automated approaches to prior authorization.

And so my first question would be has minimum necessary concretely been a big deterrence in the sense that there have been cases, corrective action plans, fines, other direct enforcement that has put an effect, an effect of scaring people from further sharing interoperability?

And then my second question would be, to the extent that just speaking from the perspective of the privacy confidentiality security angle, to the extent that there was say hypothetically either federal statutory or regulatory relief with respect to minimum necessary limits on sharing of data, would such relief or such regulation also need to be coupled with preemption, either explicit or implied, of state law?

But I would imagine there are state laws that are also governing in this area. We know the default with respect to HIPAA is that HIPAA is the floor and the states build on top of it. I am sorry for the two complicated questions. But I just wanted to put those two out there in

case anyone wants to comment on them. I particularly also just wanted to thank Pam for such a really very helpful, very clarifying presentation on some of the big issues that AI is creating in health care. Thank you.

MS. DIXON: I am going to take a shot at those two questions. I will need help with them as well from people who have some case studies.

If I might respond to the earlier question just very quickly, one of the best practices in all of AI is to retain a human in the loop. That is across sectors. That is in facial recognition. That is in biometrics. It is written into the Department of Justice rules around facial recognition. It is written into almost all the AI that I know of. So human in the loop is a really terrific principle.

And as automated as we get, I can tell you one thing that I know for certain is that AI is probabilistic. It is not perfect. If we can remember that, we will all do well.

So minimum necessary, Frank, and the idea that it is getting in the way of unfettered access, I think that this is a very common belief. And that is why I am so focused on evidence-based privacy. If you can envision a situation in which there is literally no constraint

whatsoever on access to this data, this actually used to exist in India in regards to its system with the Aadhaar.

And that system was changed because unfettered access created extraordinary liabilities and trust problems and horrific mistakes and health care mistakes I should add, as well as very significant problems with exclusion, which was the strangest thing. It is because when there was more data to analyze, in that particular context, there was a lot more exclusion. So Frank, I have written about that in Nature Springer. I can talk with you more after about that.

So I do think that there are kind of ideas and rhetoric floating around about how we need to get rid of minimum necessary. But I don't think there are really a lot of good studies that show both sides of it and find a balanced approach.

I don't know about in the US whether it has been a big deterrent or if there is enforcement actions. Someone else will need to respond to that.

And to your second question, if there was a new federal statute or a new regulation in regards to lifting minimum necessary limits, I think if it is reasonable and extremely well thought through and balanced, I mean, everything deserves to be looked at again. But if it was

significantly deregulated, would it need to be coupled, but with preemption of state law?

So my understanding of state law at this point, even the CCPA is that minimum necessary is really much more of a federal statute. You don't see a lot of state-level changes. It is primarily conforming with HIPAA. That is my understanding. And I would appreciate it if someone would correct me if I am incorrect.

My understanding is that the states can tinker around the edges of HIPAA with the floor/ceiling issue. For example, perhaps they can shorten the amount of time that it takes to turn in a record. I know that in California, the CMIA introduced medical data breech. They were the second state to do so. And then we know what happened. A lot followed. But it is more of a tinkering.

MS. GOSS: Thank you. Does anyone else want to weigh in on Frank's question? All right. Nick?

MR. COUSSOULE: I have a question. I am not sure if it is for Heather or for others as well. In some of the surveys, it was indicated that a lot of the providers, when it was specifically talking about 278s, didn't really know it existed or exactly who it worked.

I am not so concerned about the 278 specifically, but depending on who you would talk to in a provider's organization, I would think that they don't have to know

about, and they shouldn't really know about, this. That is kind of a statement more than a question.

But the question part would be as the technologies get better, and the processes hopefully get simpler, how do we make sure people understand, all the players in the ecosystem understand, how to make it work better? Any thoughts around that in particular? Again, less about the 278 because I am not sure that is actually the right answer necessarily. But regardless of what that solution would be, technical solution, process solution.

MR. EISENSTOCK: I think you make a valid point. We actually talked a little bit about this earlier, which is from the provider practice perspective, the technology decisions are often being made by their vendors. It is the EHR vendor. So we had all this conversation about the 278 and these other technologies, it is great. That is something that needs to be done at some level.

It comes down to the actual people and the practices and the hospitals doing this function, that should be transparent, and it is to them. So that is why it is beholden upon the vendor community to be up to speed and really be part of this conversation. We have brought them into this very much so because we think it is not going to be successful for us to make any changes without their involvement.

MR. COUSSOULE: How do we ensure that the vendor community is getting the appropriate feedback from practices, the providers, to make sure the solutions work?

MS. MCCOMAS: It is a great question. It is kind of the tag team on what Jay said first of all. Yes, I hope the physicians aren't wasting their time from learning what a 278 is. We don't want them to spend any time doing that.

I think that Jay's point about vendor access is really critical. In our survey, it was asking specifically about pharmacy, prescription drug, electronic prior auth, which is something that is more widely available. Only 21 percent of physicians said they had access to that in their EHRs. It gets into questions about how vendors are deploying it, does it add cost, does it require buying an upgraded version to get it? I think that is a huge thing.

From our perspective, we at AMA certainly take our role in educating physicians about what technology is available very seriously on the pharmacy side of the house because it is something that is at least out there. We do have a three-part video series educating physicians about how to use the technology.

It is not branded at all to a specific EHR product. But making it clear this is something that is in your EHR. It is available on e-prescribing. It makes

things easier. It relies on conditional logic and answering questions, that sort of thing.

We would love to be able to make more videos. My staff would, I am sure, about doing that for medical services. But frankly, I don't know what I would educate physicians on right now about medical services. What would I tell them to do? Their vendors probably don't offer the 278. What attachments? I mean, what would we tell them to do?

Certainly, I can easily say that we would be happy to educate physicians and staff on the availability of the technology. But it has to be available. And in our video series as well, we do say at the end, part of it is definitely creating vendor demand. Vendors don't build things if people aren't asking for them.

We say to our physicians and our staff who are watching the video at the end, ask your EHR vendors about this. Ask about this technology. Let them know that you want it, right? But it does get into a cost issue. I know that several of the pharmacy EPA vendors offer that free to EHRs.

But it is not necessarily free when it gets to the practice. And we know that so many small practices are financially strapped already for resources. And certainly,

they want to automate the process, but they have so many competing needs.

MS. GOSS: I am not seeing any questions around the table. Any more on the phone?

So one thing I just ant to make sure is I want to ask Pam when Frank asked the question about minimum necessary, am I appropriately linking his question with your phrase of data minimalization? Or do you mean something different than minimum necessary when you use the data minimization?

MS. DIXON: That was a good catch. Thank you for that. So data minimization is kind of the replacement term for that, that is being used in other regulatory contexts. So apologies for launching that on you. But yes, they are generally the same. There is regulatory backup for the prior, though, as well as the latter. They are very different legal context. Data minimalization is associated with much stronger regulation.

MS. LOVE: So minimum necessary and data minimization, whatever you call it, is in the eye of the beholder, is it not? Who decides?

MS. DIXON: It depends on what country you live in, but that is the right question. So if you live in Europe, there are a lot of rules and regulations around what that means.

There is also a real movement toward quote unquote privacy by design. It is not a term I love, but we will just use it anyhow. That is also a part of data minimization, which is built into a lot of the new rules and laws that are being passed in a variety of countries.

So this is, a lot of times, defined within the context of these different jurisdictions. So there is a generalizable approach and meaning to data minimization. And I would say it is more of a procedural approach and more of a goal.

Whereas if you look in the US, you are going to have HIPAA, you are going to have the Fair Credit Reporting Act, you are going to have the different sectoral approaches, as well as the Privacy Act of 1974. But in the US, we don't have quite the same issues or definitions. However, I think it did creep in the California Consumer Protection Act. It is also creeping in some draft bills that I have seen in other state levels. So until the US passes some newer privacy legislation, I don't think you will see that term here as much.

But for the multi-national corporations, it is definitely creeping in because they are having to comply with these newer norms that are cropping up. It is a really good term to know and to start to take a look at in the context of jurisdiction with more of the omnibus

comprehensive data protection legislations. Because that is where it is really defined and crept up.

In that context, you have that blanket applying to all sectors. Not just the health sector. It makes things a lot different. I am into going to say it is easier. It is just different. I hope that is helpful.

It is so much to chew on. I have to tell you, industry is really having a deep long chew in California. They are not really liking what they are tasting right now. This has to be approached. I like the slug. I think a slug and turtles, these are nice things. We don't want rabbits and hares in this process.

MS. STRICKLAND: Kate, if you can just give me a little bit more on the pilot that you are doing. Just sort of what the goals are of the pilot and approximately like when you think you will be --

MS. BERRY: The automation? It has taken a lot longer than we had hoped. We thought we would launch this year. But it takes a long time to kind of educate the plans and get the plans to commit and to fully understand the vendor functionality. Because everybody has to be able to do it.

Our goals are to test, although they are real, so it is not like it hasn't been done. These are both technologies that have been used. But we really want to

have that standards-based, payer-agnostic, scalable solutions. That is kind of like really what we want to look at. We really want to understand the impact on the patient, on the practice or the provider and on the plan. And we really want to understand that impact.

So we are right now working with RTI on the study design. So what are the measures going to be, how are we going to gather that data, who can provide it? Is it the vendors? Are we going to survey practices? And we are trying to have as few measures as possible because I think less is more. It will be too overwhelming if we try to do too much.

We are hoping to launch like sort of flip the switch, if you will, to go from manual to electronic, Q1 2020. It won't be that simple, but like generally. And then we will run for six months roughly with kind of a data pull at two or three months to kind of make sure the process works and have a quick look. And then have a final data pull after the six months.

So we are allowing time to kind of like get used to it, workflow, et cetera. And then produce the report by the end of next year. That is kind of like the timeframe and goals.

MS. GOSS: All right. I am not seeing any other questions. Go for it, Heather.

MS. MCCOMAS: On your automation pilot, on the Availity specific one, so you indicated that is going to be a multi-payer portal project. And to me, that was a little alarming. And April and all of you have heard me and other providers squawk about portals.

But the concern is obviously having one portal is better than many. But still it requires physicians and their practice staff to reenter data from the EHR. It is basically creating and redoing data entry. Is there any way that project would link up to EHRs and actually embed in EHRs?

Especially all this talk about FHIR and standards, is there some way that that pilot would actually involve direct transactions between providers and health plans? Or can you give a little bit more specificity around it because it was kind of presented as a portal project? Thank you.

MS. BERRY: I will say, as I think has been said a few times, like on the prescription medication side, we have a little bit more mature infrastructure, a little bit simpler, more mature standards. On the medical, surgical side, despite our RFP, despite 15 proposals, the solutions, as I think you probably can appreciate, on the medical surgical side, the standards are complex. There are very

few vendor solutions out there that offer anything. But I don't want to be advocating for a vendor.

On the Availity side, it is on their roadmap as I understand it, to integrate with EHRs. But that is not currently available as part of the prior authorization process. So we wanted to look at prescription meds, but we wanted to look at the all other category, too. And what they have is the multi-payer portal option. I think down the road, and I don't know the timeline, but my understanding is they plan to integrate with electronic health records.

MR. COUSSOULE: I can tell you that is the plan because we work with one.

MS. GOSS: Yes, and there are a lot of plans, but we are also waiting for the actual standards to be mature to the point where they can actually be used and rolled out. There are a lot of entities that have committed to that.

MR. RUCKER: Those are both spot-on points and issues. I think the US CORE data for interoperability, we hope the proposed rule, that will be two years after the rule is finalized. I would encourage certainly in the experiments that part of the sub experiment is to see whether that is an adequate amount of data and/or what is missing to move ourselves to a fully automated process, so

that we don't just automate the payer end of it with a portal.

But yet, leave the providers sort of in essentially a manual world because I think that is not going to work. I would throw out that, and maybe this gets to what Pam was alluding to, but there is probably enough inference in the US CORE Data for Interoperability for better or worse that you can probably reliably do prior auth on a good chunk of stuff from what you can infer there is my guess.

Even though it may not be exactly a typical prior auth, you know, how many times they had a prior surgery. You will probably be able to infer prior tests, hospitalizations, meds. You will be able to have a pretty robust risk profile on a patient that you can do. You can rethink prior authorization from just these hard-wired algorithms to probably more perform and predictive algorithms. So I would just throw that out, the timeline and the proposed rule two years from now to the multi-national. Europe has some very similar things on an international patient summary that looks very similar for anybody here who has a sort of more global interest, looks very similar to the USCDI as it turns out.

MS. GOSS: One last question from Bill Stead, and I think we are going to pivot to the ONC NCVHS discussions on what is next.

DR. STEAD: You mentioned that the drugs are relatively well worked out. My gut is that the specialty drug is going to break that. And maybe I am wrong. But the amount of clinical information you are going to need to deal with the decision around the high-priced drugs is going to be equal, if not more, than you need for high-cost imaging and certain procedures.

And so I don't know if there will end up being some way that we could use that example to tease apart what it takes to make the basic transaction flow work, which is in place for what happens when you then layer on the need for clinical information that I doubt can fit in the existing prescription pipeline. Is that right, or am I misprocessing?

MS. MCCOMAS: I think you are right. I think this is why a lot of people have said technology can help a lot. But it is not panacea. I do think specialty drugs certainly can get more complicated because there may be some covered in the medical benefit and some covered in the pharmacy benefit, for example. So it is kind of like all those systems have to talk. It is definitely complicated.

But I think for typical prescription medications, we can do much better. Yes. But I totally agree with what you are saying.

MS. GOSS: So we have a choice to make. I am going to ask Don and Bill to weigh in on this in particular. We have typically an opportunity for public comments at the end of our meeting, which will be tomorrow. However, it appears that we have some folks in the back of the room who may be interested. Would you be willing to accommodate a 10 or 15 minute usurp of our discussion time to take additional public comment?

MR. RUCKER: I love public comment. It is always helpful.

MS. GOSS: Hopefully, the crowd will not let me down in their opportunity to take advantage of the request that we heard from staff that there may be an interest in some public comment from those who have been so steadfast in attending and staying awake during this long and intense day. So Bob?

MR. GELLMAN: I am Bob Gellman. I just wanted to make a comment about the data minimization and minimum necessary point. Under HIPAA, minimum necessary applies to disclosures and not to all disclosures. There are a number of disclosures that are exempt from the minimum necessary rule.

Data minimization is a much broader concept that applies at all points of the process. And what is significant particularly here I the context of HIPAA is HIPAA implements all the fair information practices, but not the collection limitation principle. The policy, I assume, and I have always assumed is, that HIPAA doesn't want to tell doctors what information they can collect for treating patients. That is just a thought about how to navigate those two different concepts.

MS. GOSS: That you, Bob. That is particularly helpful, especially knowing your background with the committee and your amazing work in our environmental scan that supported our beyond HIPAA privacy work that we undertook in the last several years.

MS. HAUFFMAN: I am Laura Hauffman from the American Medical Association. My question is for Pam. Thank you so much for your remarks.

I was hoping that maybe you could provide an example of some of the harms you talked about in terms of the exclusionary effects that a lack of privacy can have for patients. And if possible, particularly provide examples in the prior authorization space and how important it will be for perhaps data minimization to be really taken to heart when it comes to automation.

MS. DIXON: I am going to give you an example from India. I don't know if any of you know this, but in India in 2010, they began installing a system called Aadhaar. It was the world's first national extraordinary, end-to-end, complete biometric identity system. It was linked to all services in the country. Finance, health, everything. You couldn't be born without an Aadhaar, and you couldn't die without one either.

Now, I lived in India for a total of a year studying the system. And I wrote up my results in Nature Springer. It was peer reviewed and made it into the 2018 landmark Supreme Court decision on privacy in India.

And one of my case studies was on the health care issue in Aadhaar. And what happened, to answer your question directly, what happened is that something unusual occurred. I can promise you, the goal of those who created Aadhaar was to help people and to lift people out of poverty. They had good intentions. They really did.

But when you have a system with 1. 2 billion people in it, there are certain scale effects that begin to happen. And one of the scale effects that happened is India is a country with a lot of human trafficking. And when people who are victims of human trafficking are in India, they had often been kidnapped from other countries. So when they were in India and trying to seek health care,

they were forced to get an Aadhaar card before they could get health care because Aadhaar was linked to health care.

And the reason that everyone was so insistent was so that people could get their quality of care, and their data was fed into this enormous, giant fire hose, no pun intended, of data. And no one wanted to miss any data at all. So as a result, there was this extraordinary chilling effect where victims of human trafficking who wanted to escape that life literally did not because of the Aadhaar system.

And this was a situation where maximum necessary and a lot of identification necessary really chilled the effect. And it was one of the reasons the Supreme Court decided to disrupt that progression of linking identity to service, linking services to requiring full information, downloads and no problems there, no barriers.

And what is happening right now in India is they are putting in barriers, which is so intriguing. I just had a meeting in Singapore in the financial sector about how they are putting in barriers to reduce the data flows.

All I am saying is that after seeing a country with the fire hose, and knowing that now they are trying to install barriers to create trust back in their system, including their health care systems and their financial system, I have seen the other side. That is all. But I

can tell you a lot more about that case study. And there is a lot of data associated with that study.

MS. WEIKER: I have three or four comments. a couple of things, in regard to specialty, we have a whole workgroup in NCPDP now devoted to specialty pharmacy. One of the items we are looking at is the, is it covered under the medical, or is it kind of covered under the pharmacy benefit because that is a big to-do in specialty pharmacy.

The script transaction, the version 2017071 does support clinical data. It is more of a conversation type of transaction, if you will. It is capable of doing real time, as well. But it will support clinical data. And in fact, though we don't like to admit it, it will support an attachment if necessary embedded with it. It is not a separate transaction like it is with the X12, whether it is a 275. It is with the actual script transaction.

Like I said, we have a whole workgroup around specialty. And we have task groups associated with dealing with some of the issues. One of them is inventory, which Cathy mentioned. So anybody can join any of our task groups. You don't have to be a member. So if you are interested, just go out to your website and join.

A couple of other things around some other statements made earlier. The telecom standard, version D.0, the prior authorization transactions within that

standard were meant from a pharmacy, pharmacists point of view or prior authorization to a health plan. They were never built for a prescriber, so to speak.

There are some Medicaid programs in the country that have a very limited number of drugs that they will allow a pharmacy to dispense, so to speak. And they require prior auth. So they use that transaction.

But in regard to the prescriber, what most are talking about, they used the script standard. We did look at the 278 transaction. And somebody mentioned the pilot that we did with AHRQ and several other. It doesn't work for pharmacy, period. The script standard is what we support and what we advocate. Thank you for allowing me to make comments.

MS. HINES: Are there any other comments in the room?

PARTICIPANT: Hi. Everything that was said on specialty medication is correct. But just to underscore the urgency there, right now, there are estimates that in 2020, specialty medication will account for about 50 percent. Some say 60 percent of prescriptions. And so whereas for regular prescriptions, we have made a lot of headway with EPA.

We are going to see more and more burden on providers, which is dealing with those medications. And so

it does need to be looked at it and is an important thing not to overlook. Thanks.

MS. HINES: We don't have any comments on the zoom dashboard, and nothing has come in by email. I will just close by saying there will be an opportunity again tomorrow afternoon. I can't guarantee it will be at 2:30, which is what the agenda said. It will depend on where we are. But there is a second opportunity. You can always email if something occurs to you after the meeting closes to NCVHSmail@cdc.gov.

MS. GOSS: Thank you, Rebecca. I think we will now pivot to what is next discussion between NCVHS and ONC. Thank you again to your panelists for your outstanding commentary. We appreciate those that provided slides. I know there has been an interest as to knowing how to access those. And my perception, correct me if I am wrong, Rebecca, is that those will be posted to the website. So all of us will be able to pull those slides. Maybe not.

MS. HINES: So we do not have resources right now for quick 508 compliance work. What I advise people is to email us at NCVHS mail and CDC.gov, and I will email slides to anyone who requests them. And at some point, we will get them made 508 compliant. But our resources were greatly reduced, and that was the first thing that got cut.

Agenda Item: Follow up Discussion with NCVHS and ONC

MS. GOSS: A lot of content today. A lot of food for thought. I think that there has been a lot of synergy historically between ONC and their federal advisory committee, as well as NCVHS's objectives. We are focused on wanting to improve the outcomes for citizens, the safety of the care that they deliver and to garner greater efficiencies within the information exchange processes and the costs in the health care system.

We have been talking a lot about convergence over the last year. Today's focus was on prior authorization. I think we really wanted to take this step today to do a check-in with the industry. They have been doing a ton of work to try to solve the burdens and issues around prior authorizations by taking a deeper dive into the matters, doing surveys and pilots.

And I think we wanted to use this last block to figure out what this latest intel may mean to us and how we may proceed, including some potential for a deeper dive collaboration with the industry on problem-solving. That is kind of the set-up.

MR. RUCKER: Obviously, there is a ton of things to consider here. This follows what I think is always the case for all of us in this field. Every time you dig into

something, you learn new things you never expected that make total sense in the context that you just plain simply weren't aware of because all of our worlds are finite.

I think there are a couple of opportunities that are probably worth sequencing just based on things and throw those out for consideration. Some of these, I think, fit naturally into the NCVHS plus ONC type of turf. Some of them I think sit in related domains.

One area that is also, I think, certainly part of the CMS national standards group and our colleagues from WEDI is thinking about a trajectory. And this will be a while because I think FHIR is still very early. But is there a way to graft onto the X12 processes some of the richer clinical information that we anticipate to have available in FHIR over time? That is a multi-year thing.

But I think it is something for WEDI and maybe even CAQH to think about. What would that look like technically to do that? My computer science sense tells me it is quite doable from a computer science sense. From a policy business investment, obviously it is a multi-year trajectory. There are a lot of people who have operationalized X12 transactions in every part of the revenue cycle. So this will be a long process.

But if we can put these APIs, which we are doing or proposing to do in the Proposed Rule, if we, over the

next couple of years, can have certainly the USCDI data available, what would be the way of getting that into an X12? And I think it is my understanding of looking at the X12 specs, is there are ways to merge those two things that are technically possible.

I think that is one fairly specific thing that we might as well, I think and probably WEDI I am guessing, is probably the point for that. I am looking over at the WEDI team. I think that is one specific thing that certainly where NCVHS' authorities would come to play there. I think maybe the second one is still a little bit early in terms of research, but was identified at our March meeting.

Like Ken Comodo (ph.) from the University of Utah and a number of other folks, a number of the vendors on CDS Hooks. I am not saying that CDS Hooks is a solution to decision support. But I think thinking about exploring some of those types of things would be good. Maybe that needs to be part of some type of a research agenda that is funded.

I think certainly as we are moving, the secretary is very interested in the interoperability work. The administrator is very interested in the interoperability work. So maybe there are some ways to prioritize a couple of the sort of key point technical questions to address here.

But I think we are going to have make progress on both of those things as an underpinning to have that seamless end-to-end state and not just pump the innocence into portals. So the people who are left in portals type of thing to sort through that manually. Those strike me as a couple of the key things. There is probably on the payer side, probably the private payer side, as I am looking at Lorraine.

But maybe this will be part of what Kate can do is looking at how many decisions can be made with the USCDI. So we do have sort of a limited dataset. What can be offered there? What would be the real world performance of prior auth with that type of data? Again, my gut tells me that the data that has actually being acted on today is probably a fairly small set of data.

I am sensitive to Bill's point that when you look at the biologics, those biologic measures, all the immunology tests that all of us as clinicians, like what was that test again? I have sort of struggled to learn or given up on learning over the decades. That may be richer, but it may not be. And it is worth at least understanding what that is.

I think there are a couple of key areas there where we can work together in a very rich way. We have a process at ONC. Over time, we will be expanding the US

CORE data for interoperability. I think we have first got to get it up and running before we worry much about expanding it. But I think there would be that process. So those are my thoughts.

MR. MASON: I was thinking based off of some of the data today that was presented, and we now have a better idea around what are some of the high priority, high volume, prior auth use cases that we can think about and sort of tie to does the USCDI support those? And are we able to have in a structured way the right clinical data is what I was thinking.

MR. RUCKER: Any thoughts or comments from the committee on how this might work? Just looking around the room in terms of stuff that strikes you as yes or ouch?

MS. LOVE: Last week, this brings it down off the national platform a little bit, but there were some interesting things going on with the HIEs and some of the state data agencies. I have the slides here. I was looking as you talked, and they are bringing in a lot of different information and then blending or using claims data either for back end analytics or for trigger lab tests for certain labs. What is that patient's history going back?

And doing some of this predictive and retrospective analytic, but also some of the other

reportable conditions in a state. And then running it through the HIE and thinking more in an integrated way. I don't think it goes at all with anything you said. It is just a different way of putting the data together I suppose. But I think lessons learned are out there.

MR. RUCKER: The HIE is interesting. We are trying to get some more of the public health things into the TEFCA framework, which is part of CURES, The Trusted Exchange Framework Common Agreement, which is what Congress sent out to have the various information exchanges talk to each other.

There I think there are obviously a lot of state laws on reporting of communicable diseases, a lot of issues just even on top of the usual privacy concerns there. We have heard from the state agencies that a lot of them have minimal resources to really engage on modern computing. I think they have a lot of sort of idiosyncratic homegrown platforms. This has been an issue with even things like immunization registries and prior work.

So it is out there. The HIEs obviously are, and also in addition to the HIEs, a couple of private companies who are trying to get into that integration of backend data. A lot of that is driven by the ACO. Not prior auth, but by the ACO requirements, which are similar. Have a

little bit of a similarity to prior auth. But they are not identical.

MS. GOSS: So along the lines of a late-day comment, I noted the commentary around attachments. And I worked on attachments with X12 and HL7 in the early 2000s. And then I was appointed NCVHS, and it was the first meeting topic. And I thought, we haven't solved this yet. And then we did some more work on it. We wrote some more letters on it. And it is not advancing.

We have made recommendations as a committee to HHS on adopting attachments reg as expected under the original HIPAA framework. And so I think that there is some level of rethink in today's market, with today's capacities, like USCDI, like FHIR.

I think we need to figure out as a part of this larger use case conversations what is really the best automated way in a privacy-considerate manner to get data exchange between the payers and the providers more effectively. And clearly, we may have those standards emerging out of the HL7 community or other areas.

But I think we, as a committee, need to reconsider those recommendations and think about obligations moving forward. And I would hope that some of the work that we would do over the next maybe 6 or 9 months would help inform some of those because it is troubling.

DR. STEAD: I was headed exactly the same place. I think one of the first things we actually could do would be to see if there is consensus in the industry to let everybody know we are not going to do an attachment standard. I don't think we could do that if we didn't communicate an alternative path. Not an alternative prescription, but an alternative path.

And I think what Don suggested, because it sounds to me like it fits with what we heard from X12 earlier about the way they can make it, so you can put their metadata into -- you can make that work. It is a FHIR packet that you could then drop into an X12. I may have been dreaming that.

But if not, I think it is still possible from a computer science point of view. And because I could see a path forward, if we could let the industry know we are not going to continue to hit our head against attachments. 20 years is long enough. And if you want the kind of clinical data it takes to deal with a significant decision, it will never fit in an attachment as we think of it.

And therefore, we are much better off pulling in the appropriate minimum necessary targeted information we need to support that transaction with something such as FHIR if USCDI or an extension of USCDI will in fact support

it. So you have actually sketched out one alternative path.

So rather than boiling the ocean, we could do a first step, which I think the idea of having the payer community sit down and look at USCDI and say, are there sufficient PA decisions we can handle this way that that would in fact become something we could work with? And if we could work with X12 and WEDI to figure out the degree to how heavy a lift it would be to do the pilots of then bringing that in, you could maybe in a year have some reasonable pilot of an alternative path that would work.

I think the sooner we communicated that we probably need to go some other way, and we need to rapid cycle figure out what it is, maybe in six month cycles until we have something that is beginning to work, I could see a way to begin to break this thing open. I think we need something along those lines if we are going to meet your dream.

MR. RUCKER: Part of this is the challenge between structured and free-text data. I mean, when you look at these things, I don't know the whole history of the claims attachment story. I have tried to learn a little bit of it. I think my guess is that the USCDI things will probably be more mature a bit before we have the pure,

unadulterated NLP types of things that would need to be gotten out of a claims attachment.

And then even then you would need, as Bill suggested, a fair amount of metadata. It is worth pointing out that as part of USCDI, there are clinical notes. So the USCDI thing actually does have things that would logically sit within a claims attachment.

So it may be the better part of valor to just put in the USCDI and get that data there. Then in a separate one-off standard. But I think the structure data is going to be easier to get at and more defensible for just the black box transparency reasons that Pam talked about in her comments.

MR. LANDEN: One idea I heard earlier today was actually from Kathy Shepherd talking about X12 and X12's ability to support other structures, other syntaxes, and she listed JSON and XML and FHIR. And if we think about X12 transaction as a HIPAA standard, but in those other syntaxes, the data payload, the metadata, that may give us a lot of the flexibility we are looking for and still we could tweak a HIPAA regulation to allow those different syntaxes without specifying that you need to use the 278 and the current EDI format.

I need to think a lot more about that and find out more about that from some of the X12 gurus. But I am

seeing that as a possible evolutionary path towards this greater convergence idea that we are talking about.

DR. STEAD: We are about out of time.

MR. COUSSOULE: Just one other comment, I think that if we can identify an appropriate subset of volume-based transactions and compare that in, instead of trying to solve all of them at once, I think I am with you. I think we can move a lot faster.

I think we have got to get away from the it has to be perfect, or we never start. We have to be thinking about the very targeted use cases and models, and then making sure, and I think we can make a lot of progress.

DR. STEAD: So if what we are asking the payer community to do is say, what are the things that you want prior auth on that we can handle with current UCDI, what can we handle with the roadmap, those two become the first two buttons we would be begin to tackle. That would focus it.

MR. RUCKER: Yes. It is probably also worth syncing up with some of the Davinci folks because there may be a win-win there. They are putting programming resources into some of these things. I don't know what the mechanism is with NCVHS and how you would do that. We are happy to work with that through ONC. We do a lot of stuff with them in a wide variety of contexts.

MS. GOSS: In full disclosure. I have a conflict of interest now that he just mentioned Davinci. I can also assist with that.

I do think that I would like to go back to Bill's comment regarding the signaling to the industry. I think that we need to not only signal to industry, I think we need to signal the regulators that we have written letters to ask them to act and to do our own homework on double-checking the regulatory plan that they put out and the federal registry case that is advancing because we don't want to waste federal resources unnecessarily.

I think we have had a lot of good ideas here today. I think we need to take them away and come up with a concrete action list, synthesize down what we think is feasible and move on that fairly quickly. I do believe that we have a follow-up call already scheduled between the standard subcommittee representatives and ONC to take a deeper dive into what we have heard today and start to create a plan.

But I also think that before that call will happen in the next couple of weeks, the full committee will have an opportunity to discuss the workplan tomorrow. And I hope that we can all think about this in our sleep and come up with some opinions before we get into that afternoon discussion tomorrow.

DR. STEAD: Thank you. We really appreciate the engagement with ONC and the panel with the presentations and conversations. Thank you. We are adjourned.

(Whereupon, the meeting was adjourned at 5:50 p.m.)