



Collaboration of the Health IT Policy and Standards Committees

Draft Transcript

May 17, 2016

Presentation

Operator

All lines are now bridged.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a joint meeting of the Health IT Policy and Health IT Standards Committee. This is a public meeting at there will be time for public comment before lunch and at the end of today's meeting. As a reminder please state your name before speaking as this meeting is being transcribed and recorded. We'll take role by going around the room and we'll start with Lorraine.

Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health & Human Services

Good morning, Lorraine Doo with the Centers for Medicare and Medicaid Services.

Jonathan Nebeker, MD, MS – Associate National CMIO for Strategy and Functional Design – Department of Veterans Affairs

Hi, Jonathan Nebeker, Department of Veterans Affairs.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Andy Wiesenthal, Deloitte Consulting.

Christoph U. Lehmann, MD, FACMI, FAAP – Professor, Pediatrics & Biomedical Informatics – Vanderbilt University School of Medicine

Chris Lehmann, Vanderbilt University.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Jitin Asnaani, CommonWell Health Alliance.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute

Anjum Khurshid, Louisiana Public Health Institute.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Josh Mandel, Harvard Medical School.

Angela Kennedy, EdD, MBA, RHIA – Head of Department & Professor Health information Management – Louisiana Tech University

Angela Kennedy, Louisiana Tech University.

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Kim Nolen, Pfizer Pharmaceuticals.

John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense

John Scott, Department of Defense.

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Carolyn Peterson employed by Mayo Clinic but here as a patient consumer representative.

Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Vindell Washington, Principal Deputy, ONC.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Jonathan White, Deputy National Coordinator, ONC.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Arien Malec, RelayHealth.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Paul Tang, IBM Watson Health.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Kathleen Blake, American Medical Association.

Paul Egerman – Businessman/Software Entrepreneur

Paul Egerman, retired CEO.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Anne LeMaistre, Ascension.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Leslie Kelly Hall, Healthwise and the Informed Medical Decision Making Foundation.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Eric Rose, Intelligent Medical Objects.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

Floyd Eisenberg, iParsimony.

Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Elise Sweeney Anthony, ONC.

Jennifer Brown – Office of the National Coordinator for Health Information Technology

Jennifer Brown, ONC.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And on the phone we have Donna Cryer.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Yes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Donna. John Derr?

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

John Derr, long-term post-acute care and JD & Associates.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, John. Scott Gottlieb?

Scott Gottlieb, MD – Resident Fellow & Practicing Physician – American Enterprise Institute

Hi, Scott Gottlieb with the American Enterprise Institute; thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks, Scott. Gayle Harrell?

Gayle Harrell, MA – Florida State Representative – Florida State Legislature

Gayle Harrell, State Representative for Florida.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And Liz Johnson?

Elizabeth Johnson, MS, FHIMSS, CPHIMS, RN-BC – Chief Clinical Informatics Officer & Vice President, Applied Clinical Informatics – Tenet Healthcare Corporation

Liz Johnson, Tenet Healthcare.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Liz. And Wes Rishel?

Wes Rishel – Independent Consultant

Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Wes. And Karen, Karen can you tell me how to pronounce your last name?

Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition

Sure, good morning, this is Karen van Caulil and I'm with the Florida Health Care Coalition.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks, Karen. And Kevin Brady?

Kevin Brady, MS – Group Leader, ITL Interoperability Group – National Institute of Standards and Technology

Kevin Brady, NIST.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And is there anyone I missed on the phone? Okay, with that I'm going to turn it over to Kathy to make some ope...well, Kathy to review the agenda and walk us through what we're going to discuss today.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Great, thank you so much Michelle. And so welcome to all the members of the committee who are here in person and those on the phone and also to our guest speakers. We're looking forward to a very enlightening and stimulating agenda today. I'd first like to ask for approval of the minutes of our meeting of April 19?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So moved.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Do we have a second?

W

Second.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

And all in favor of the approval of the minutes as presented to us?

Multiple speakers

Aye.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

And are there any opposed? Thank you. So the minutes will then be approved. I'm next going to briefly turn it over to Paul Tang, to my right who's going to talk about some of our members who will be exiting and transitioning off of the committee.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thanks, Kathy. A couple of our members, David Lansky and Alicia Staley are going to be leaving after their term, and we have some new replacements to be announced. David Lansky has been the CEO of Pacific Business Group on Health for quite some time now and he's been...had been on the committee since its inception, always provides insightful perspectives according to the purchaser, and I think the purchaser and the consumer and has been largely focused on getting us better measures of outcomes. And you'll see in MACRA that's another theme. So he's had many roles on the committee as Chair of the Quality Measure Workgroup at different points in time and so we really appreciate his efforts on the committee for the duration of his tenure. He also served in Meaningful Use Workgroup is what we called them in the past. So really thanks to David.

Alicia Staley is a three-time cancer survivor. She was a representative of consumers on the committee and she...since 2013 and although she's going to be departing from the committee, she'll continue to lead the patient engagement efforts and work on quality and safety initiatives. So thanks to Alicia as well. And that's about it.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

So thank you to both members for their long service and as members' transition off, we're also happy to welcome three new members of the committee and pleased that Caroline Peterson is able to join us today. Carolyn is the Senior Editor for Mayo Clinic. Org at the Mayo Clinic in Rochester, Minnesota. She is a 30-year pediatric cancer survivor and has served as consumer representative for multiple groups including the Food and Drug administration's anesthesiology and radiology...excuse me respiratory services panel, the National Cancer Informatics Program and the Improving Healthcare Systems Advisory Panel of the Patient-Centered Outcomes Research Institute, PCORI .

She is currently a member of the ethics committee of the American Medical informatics Association and she has published articles and presented on issues related to patient and consumer access to health information. Ms. Peterson received a Masters of Biomedical Informatics from Oregon Health and Science University. So welcome to Carolyn into our committee; would you like to just make a few remarks?

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Thank you for your kind words and for your welcome today. I really look forward to the opportunities to work on this committee and contribute greatly for Americans in healthcare. Thank you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Thank you so much. On the phone is Karen van Caulil, PhD. She's President and Chief Executive Officer of the Florida Health Care Coalition, which is a business coalition on health representing 2 million individuals. She is currently Chair of the Board of Governors of the National Business Coalition on

Health. She is also adjunct faculty in the Department of Health Management and Informatics at the University of Central Florida College of Health and Public Affairs.

And she was responsible for developing the University's Regional Extension Center through 2011. She was appointed by the Florida Secretary of State to the State Consumer Health Information Policy Analysis Advisory Committee. She received her PhD in Public Affairs from the University of Central Florida. And Karen, I'll open it up if you'd like to just share a few remarks with the committee.

Karen van Caulil, PhD – President and Chief Executive Officer – Florida Health Care Coalition

Thank you very much, I'm really looking forward to working with you all; been a few years since I've been working with ONC through our work at the Regional Extension Centers. So now that I've moved on to running a business coalition on health, it will be interesting to connect the dots from what I've worked on in the past and what we're doing right now with David Lansky and his organization and the National Business Coalition on Health. So thank you very much and again looking forward to working with you all.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Great, and we're looking forward to working with you. And again like many on this committee, many different perspectives that each individual is able to bring to our work. And then the third I should say new but old member, formally on the Health IT Standards Committee is Jamie Ferguson, who's President of Health Information Technology Strategy and Policy for Kaiser Permanente and he is a fellow at the Kaiser Permanente Institute for Health Policy.

He is responsible for health IT, informatics standards, developing Kaiser Permanente's health IT priorities and policies and responsible also for government and industry relations related to health IT. He serves on a number of national and international health IT organizations including committees of HL7, ISO and the World Economic Forum. He also serves on the US Department of Health and Human Services Health Information Technology Standards Committee, but is changing or is going to be serving on the Policy Committee. He's been Chair of its Clinical Operations Workgroup and Chair of the its vocabulary subcommittee.

Before joining Kaiser, Jamie was a research investigator in the Department of Molecular Biophysics and Biochemistry at Yale University's School of Medicine where he studied renal and hepatic protein structures and pathways. His BS degree is in molecular biophysics and biochemistry from Yale and he has studied computer science and economics at MIT. So I think again, a member of the committee who is a Renaissance person and will bring a variety of interests and experience and expertise to our work. So thank you to all three for joining us.

And Michelle, I don't think I heard Jamie sign into the call, so we'll look forward to seeing him at our next meeting. At this point I will ask our leadership from ONC in Vindell Washington if there are remarks he'd like to make before we embark on our first agenda item.

Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Thank you and I'll make this relatively short and to the point. I'm really excited about the session that we are scheduled to have today. I think that our work in the combining the committees has been a very positive thing as we look for and again thank you all for your service.

I do want to underscore just one point. I think that as we talked about the importance of interoperability as a foundation for some of the work we're doing within the administration, we have sort of slotted our work streams into three different areas; one of them is really a technical standards-based discussion that we've been having over the course of time.

The second is really around the culture of change and whether or not we can make it more the norm that this information is shared and shared freely. But the third and we're happy to delve in deep today is really making sure that there is alignment from a business perspective. We're really happy to have our colleagues from CMS to join us this morning to have some discussion about it.

We've had some heavy lifting that's been done on their part and we've tried to support them in this effort. But I think as you think about it contextually, it's really around making sure that we align all of those streams of work in order to push this forward. Looking forward to that activity today as well as the report outs and recommendations from our task force, our API Task Force and others. So I think it's going to be a great meeting and thanks for the opportunity and thank you all for your service.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Thank you and then Jon White remarks?

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Very limited. First thank you all for taking the time and effort to get yourself here to Washington. I had hoped we'd have a break in the rain for you, alas no, it came back here for you. But that's okay. You know, I'll just...I'll echo and slightly elaborate on what Vindell said. You know, as I look down across the presentations you're going to hear from today, aside from the fact that they're some of my favorite people, you're really, you know going to be hearing from people that are grappling with, you know some of the key things that are pushing us as an administration ahead.

Kate and her colleague at CMS worked awfully hard to get to the proposed rule out and so it's been, you know tremendous work on their part, in great partnership with us at ONC; thank you for that. And, she's an important lady, so I appreciate you coming to take the time and come here and spend time with us and be able to interact with our folks.

Leslie and Andy, thank you all so much not just for this particular report out, but for being willing to throw yourselves into the breach over the past several months, almost getting on a year now on something that has been significant enough that the President did a one minute video spot about Josh Mandel's work on Sync4Science. So, you know, it's something that is driving us not just as a nation ahead, but internationally is what I'm finding for precision medicine. So the work that you all have done on the Precision Medicine Task Force is a really vital piece of moving that had.

Josh and Meg, of course, you know I cast myself back to 2013...2014 and you know think about you know, where we've come from in terms of you know the JASON Report and JASON Task Force and you know, now to the point where we're kind of getting down to brass tacks about APIs, so really grateful for the, you know wide ranging and incredibly sophisticated discussion that has happened and your ability to heard those cats and kind of get us to this particular piece of the discussion.

And who doesn't like Steve Posnack; right, I know, you all love hearing from Steve. So, who is, you know, one of the most talented people that works at ONC. So it's a great day, looking ahead and so thank you and look forward to this discussion.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Thank you Jon and I think we've had a good summing up of the plan for today in terms of the agenda and also the work that will be brought forward to you and so rather than repeating that, I'll turn things over next to my Co-Chair Paul Tang to introduce Kate Goodrich.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you, Kathy. This is a presentation I've been looking forward to for a long time, MACRA and who knew it would take a circuitous route to get here through the SCR repeal. But I think it's really very, very important and meaningful legislation. If you think back to when these FACA committees were formed in 2009, one of the important tasks, at least for the Policy Committee was, or for both committees was Meaningful Use back in 2009.

And really the results are quite dramatic as the country's gone from 0 to 60 and the original swoosh from Stage 1 to 3, that swoosh from...of what we wanted to accomplish in each of the goals in terms of our recommendations, the fir...MU1 was really sort of a push state, because we were pretty much at zero and by Meaningful Use Stage 3, this is back in 2009, we were thinking it would really much be...much more be a pull stage from payment reform; we even thought about it back then. And so this is really a delight to see MACRA take such a bold move in moving the agenda forward in terms of moving from this pay-for-volume to the pay-for-value. And the things that are listed in there, the objectives and then really moving towards outcomes are really a wonderful change, I think, for the health system and for the whole country.

It's clear also as you read it that...and there's a lot of reading; but it's clear as you read it that they really listened, they meaning CMS and ONC and the administration, HHS really listened to all of the feedback. Because certainly we've been a part of it and listened to a lot of it as well, but really a lot of the things in there are responsive to the feedback that's been given to them by all parts of the country.

Some might say it's pretty complex, but then so is the United States, it's quite a diverse country and what was done here to provide the flexibility I think is really remarkable. So looking forward to one, Kate's presentation, sort of a summary...an overview of legislation. And then two, people's reaction here and our attempt to feedback...provide feedback, as is requested in the NPRM back to HHS in terms of...and for the next revision, But just wanted to thank, to echo Jon and Vindell, just to thank the HHS for the enormous amount of work and listening that's gone into, and thought that's gone into this regulation...proposed regulation. Thanks Kate.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

All right, thank you everybody; thanks for having me here today and excited to present this to you. I'm going to be presenting a fairly high level overview of our proposed regulation. It is, as Paul said, a lot of reading, 963 pages I think it is. We hope that every year it's not 963 pages, for the first year it probably did need to be; and we very much look forward to your feedback and comments. I think our approach to MACRA generally and this cuts across both MIPS, the Merit-based Incentive Payment System and the APM proposals, was really as the law required.

And as Paul mentioned, to really not just listen to stakeholder feedback about sort of the current state and what they'd like the future to look like, but to really absorb that and figure out what the pathway looks like to get us to a much better future state where the health care system can be...is transformed and that these programs actually are helpful to clinicians to practice higher quality, lower cost care to provide better outcomes for patients.

And we see our proposals as really a first step in that direction. I don't believe that anything that we have in here is the be-all, end all, I think it's going to be a progression over in time in part because of just operational realities to be able to implement everything all at once was something we really weren't able to do, but we also know that we really need to learn from implementation and learn what works and what doesn't. Some of that we know, because we have had experience with Meaningful Use, with PQRS and the value modifier and so forth; so we've learned what to do and what not to do based upon our experience with those programs. But this really is to us I think, and I think you would agree really a whole new world and a transformation. It's the biggest change really to the Medicare program in many, many, many years and a critically important one.

So I'm just going to wal...I don't know where I point this, it's, nope, there we go, okay. So...I went too fast. Okay, there's a delay; I just realized that. So the agenda is that I'm going to give you an overview of the Quality Payment Program and I'm going to dive a little deeper into the Advancing Care Information category of MIPS, because that's I think where you all have some clear interest. Going to talk a little bit...just the last three agenda items are actually very, very brief; talk a little bit about data submission, different ways to submit data to CMS and what the timeline is and then how to submit public comment.

So as you all probably know by now, we have...we're calling MACRA the Quality Payment Program and a few things to note at the outset and this, and apologies on having to use notes, because I just can't see that far, and there's a lot of detail here.

So very famously now, repealed the very unpredictable Sustainable Growth Rate and streamlined three programs, Meaningful Use for Medicare clinicians, PQRS and the physician value modifier into a single program, but also provides payment incentive to clinicians to join advanced alternative payment models. And I'm going to talk a little bit about what we propose an advanced payment model looks like.

So clinicians will either fall into MIPS or they will be...fall into advanced APMs. And as I mentioned before, we really, really do see this as the first step to a completely fresh start. We've said from the beginning that this is not PQRS Value Modifier Meaningful Use 2.0; this is something different. Yes we need to build upon what has worked, but we need to really take a hard look at ourselves and the impact on clinicians to understand what hasn't worked.

So we are listening and there is help available. So I would say, as we have developed this regulation and not just the regulation, but as we have and are continuing to develop our own internal systems, our public-facing information and future web portal, we are doing much more not only convening of stakeholders and listening to them, but you know, in the trenches user research to help us design the program, the operations, the communications and how clinicians interact with CMS, which I will say has actually been a lot of fun to sort of take this new approach. But it is...these are skills we are definitely learning and building.

We of course, you know really see this as a significant step to get to a more sustainable Medicare. CMS is responsible for the health care of 140 million Americans, and there are many, many more Americans in the future who are going to need our program. And while the Medicare Trust Fund is in better shape than it was several years ago, it needs to remain sustainable and that's one of the big...that's a major impetus for all the efforts the department is putting on delivery system reform is to get to a better, smarter Medicare.

So we want to pay for what works and we don't want to pay for what doesn't work. And healthcare information very, very importantly needs to be open, flexible and user-centric. So it has to be open and available not just for clinicians to be able to use at the point of care, but available for patients at the time that they need it in a way that they can understand it and actually use it. So I'm going to start first talking a little bit about APM's. I do want to acknowledge I have two colleagues on the phone, J.P Sharp and Patrice Holtz from the Innovation Center if there are questions about APM's that I'm not able to answer. I'm not quite as in the weeds on the APMs as I am on MIPS and so they are available to answer questions once I'm done.

So APM's are of course new ways to pay for medical care through Medicare that incentivize quality and value. And so we're talking about things like shared savings programs, bundled payments, population-based payments and so forth. MACRA actually does define what an APM is; so it defines APMs as a CMS Innovation Center model. So somethin...you know, next gen, some of the bundled payments programs, the Medicare Shared Savings Program as well, and then a couple of different types of demonstrations, including ones that are required by federal law that are less common, but they are part of the definition that Congress gave us of an alternative payment model.

Very importantly though, Congress also further defined what they called eligible APM's and we've...we're calling this Advanced APM's to make it a little bit more clear. And these have to meet certain criteria that again are highlighted within the statute. So an advanced APM must meet all of the following criteria. Number one, they have to use certified EHR technology.

Number two, they have to base payment on performance on quality measures that are comparable to those that are in the MIPS quality performance category; we do make proposals in the regulation about what comparable to means. Mainly it means any measures that are in MIPS that are being considered for MIPS or that meet certain criteria reliability, validity, sort of NQF endorsement type criteria or measures that are endorsed by NQF.

And then finally, the APM must either require that entities underneath the APM bear more than nominal financial risk for monetary losses or that they are a medical home model that is expanded under CMMI authority. So we have detailed proposals in our rule around the definition of more than nominal risk as well as our proposals around medical home models that would meet these criteria.

So how are clinicians who are part of APMs scored? Now this...the next couple of slides really refers to clinicians that are in APMs who may or may not meet the criteria to get the APM incentive. I'm going to talk a little bit how one becomes...meets those criteria. So the goal of how we score clinicians underneath APMs was primarily to reduce eligible clinician reporting burden, because what we didn't want was a situation where a clinician, because they're not necessarily certain if they're going to meet the criteria for being a qualified participant in an APM would actually meet that versus having to participate in MIPS. We did not want people to have to report twice; I think that would be just disastrous. So we really worked hard to try to reduce burden on clinicians who are part of APMs. And really if you're in an APM that you should be focused on the specific goals and the specific metrics that are part of that APM and not something separate from that.

So basically what we had proposed is to streamline MIPS reporting and scoring for eligible clinicians that are in APMs, to aggregate of those scores at the APM entity level and that eligible clinicians that are in an APM receive the same MIPS composite performance scores. And we use APM-related performance to the extent practical. So again, really trying to focus on ensuring that clinicians that are in these APMs are focused on what they are already expecting and required to do relating to quality, cost, improvement, use of EHRs underneath that APM, and so they're not being held to separate reporting requirements.

So the APM scoring standard as we are calling it, applies to APMs that meet certain criteria; they are outlined on this slide. So they have to participate in APM under an agreement with CMS. The APM entity must include one or more MIPS eligible clinicians on their clinician participation list. And the APM bases payment incentives on performance on cost utilization and quality measures. Again, that is something that occurs within the C...the APMs that are currently part of the Innovation Center.

Moving on, so the existing models that are part of the Innovation Center that clinicians who are within these models would be subject to the APM scoring standard are the ones that you see on this slide here. So the Shared Savings Program, Next Gen ACO, Comprehensive ESRD Care, the CPC Plus model that was just launched, the Oncology Care Model and of course any other APM that comes along that meets criteria for scoring standard. So these are the models, to be clear, these are the models that are in existence now that would qualify, or clinicians who are in these models would qualify for the APM Scoring Standard.

I will just say, because I've gotten this question a lot as I've been out talking about MACRA, you know the goal over time of course is to be able to bring in more types of models; there's a lot of interest from the specialty societies, as well as primary care clinicians and having models that they are able to join that certainly is the goal over time. The Physician Technical Advisory Committee or the PTAC that's been convened to review models that are submitted to them to make recommendations for HHS undoubtedly will produce models that we are able to then bring to scale. But that is something that is, you know, beginning after the final rule is published in November.

So we do believe that over time there will be more models for clinicians to participate in. There were some clinicians I think who saw this list and thought this is like this is it, this is the only ones possible and that's not true. We do anticipate that over time that there will be more models that either are suggested to us by innovative thinkers out there who want to design a model for their specialty or ones that the Innovation Center develops and brings forward. So again, just to reemphasize, MACRA does not

change how any individual or particular APM function, okay, or how it rewards value. It just creates incentives for APM participation, which is important.

So a little bit about who lands where; so this next slide shows again MACRA does provide rewards for participating in APMs. So, I don't know if I have a pointer here and if you can even see it; probably not. So if you...I'll try not to hit Paul with this...with the laser pointer. So if you are not in an APM, you're subject to MIPS; that one's easy. If you are in an APM, you may be subject to MIPS adjustments and...but you also are eligible for the APM-specific rewards; okay, if you...that's just for APMs that are non-advanced APMs. If you are in an advanced APM, you are subject to...or you can receive APM-specific awards and you may receive a 5% lump sum incentive. But that's only if you are a qualifying participant. So the law outlines very specifically what it means to be a qualifying participant in an advanced APM in order to receive the 5% bonus; so I'm going to talk about that next.

So how do you know if you are a qualifying participant? What the law says is that you must have a certain percentage of your patients or your payments through an advanced APM. So you may be participating in an advanced APM, but you may also see Medicare patients outside of that advanced APM or that are not part of, that are not assigned to that advanced APM. And what the law requires is that the first year or two, I think it's at least one year, maybe two...I think it's two years, that 25 % of your payments must be through an advanced APM. So the threshold is fairly high and that moves up to 50% and then 75% in subsequent years.

So if you meet this threshold, you have a certain...you meet the payment or patient threshold as a clinician who is participating in an advanced APM, then you are excluded from MIPS and you have the opportunity to receive a 5% lump sum bonus each year for payments years 2019 through 2024. In 2025 the fee schedule remains static, the physician fee schedule and then in 2026 it bifurcates; and I'm going to show this in a later slide, But essentially in 2026 if you're a qualifying participant in an advanced APM your fee schedule update for all of your Medicare charges is 0.75% a year and if you're not a qualifying participant in advanced APM, it's 0.25% a year. Somebody already mentioned that this is a complex law and you can see already that it is, in fact.

So we believe that in the first year that the majority of practitioners are going to be subject to MIPS. So the majority of practitioners are probably not in an APM in the first proposed performance year, which is 2017 as it's proposed. And those who are an APM may be in a non-advanced APM and if they are in an advanced APM, that they may not meet that threshold of 25%. So I think our back of the envelope calculation, which is, you know, a little better than back of the envelope is that somewhere around 80 to 90,000 clinicians will be qualifying participants in advanced APMs. So...but we'll have to see how that plays out.

Okay; moving on to MIPS. So MIPS again it's a new program, consolidates the three or streamlines the three currently independent programs to work as one and the goal of course was to ease clinician burden. I will just have a little side commentary here that the three existing programs, you know each was stood up by a different statute, and PQRS in particular was modified multiple times by various laws over time and I think as hard as we tried to align them on the backend that was actually quite difficult to do. So I will say for us at CMS, this law was a relief to be able to consolidate down to one program. So...but the law is very explicitly does take facets of each of the existing three programs to combine it into one.

So clinicians will be held accountable for performance on quality, resource use, use of EHRs or what we're now calling advancing care information and then a fourth category that is new, which is clinical practice improvement activities.

And the way that we have a tried to design the program in the first year and with our proposals is really to have a very strong focus on proposals that we think can be scaled and grown and improved over time that will improve patient outcomes; that's always number one. Number two, to reduce clinician burden, administrative burden and what it is they have to do to actually report to us. And then number three though, to provide flexibility across the categories so that clinicians can really be focused on measures within each category that are relevant for their practice.

I think the previous programs had a little bit too much of a one-size-fits-all kind of feel to them, and so we really wanted to figure out ways that we could allow clinicians to use metrics again across each of the categories that are relevant to their practices and actually work together with one another. So that what you're actually reporting on for example for quality measurement, is related to your clinical practice improvement activities, as an example.

So first of all, let's talk about eligibility for MIPS, the who participates in MIPS? And the easy answer is that if you are a clinician the bills Medicare Part B, you are eligible to participate in MIPS. In the first years of the program, again as required by statute, the clinicians who are eligible are physicians, PAs, nurse practitioners, clinical nurse specialists and nurse anesthetists, and then we are able to add other types of clinicians in future years. And so we've made proposals around that; you can see all of the different clinician types, physical therapist, occupational therapist and so forth listed there.

And this is a little bit awkward just because many of those clinicians that we can add in year three actually participate in PQRS now. And so we...certainly those clinicians are eligible to still participate, but they are not subject to MIPS in the first couple of years; so they can certainly send in data to us, but their payments will not be affected. So again, you bill Medicare Part B, you can participate in MIPS; however there are three categories of clinicians who are not subject to participate in MIPS.

First is clinicians who are in their first year of Medicare part B participation; this is a requirement of the statute. Second is another requirement of the statute that clinicians who are below a patient volume threshold are not subject to MIPS; the idea being, you know if you really don't see that many Medicare patients or bill that much under Medicare, it may not be worth your while to report to the program because we know there is certainly a cost in terms of dollars and time to be able to do that.

So what we've proposed is a low volume threshold is Medicare billing charges less than or equal to \$10,000 a year and that the clinician cares for 100 or fewer Medicare patients. And we are seeking comment on these thresholds, so very open to hearing alternative ideas for what to be low volume threshold cut-off could be. And then finally of course, certain participants, so qualified participants in advanced APMs, as I mentioned before, are not subject to MIPS. And to be very clear, MIPS does not apply to hospitals or other facilities and we've gotten this question actually quite a bit, I think in part because of the changes that we're making to advancing care information that really are only for Medicare clinicians; they don't apply to hospitals. The MACRA legislation purely is focused on the Medicare eligible clinicians.

So I'm going to say a few extra words about the advancing care information category, and obviously a lot of interest here. You've heard us talk about this a lot publicly, sort of our principals around this. As I mentioned before, we have spent a great deal of time soliciting stakeholder input on the entirety of MACRA, so MIPS and APMs, but we probably did had a very intentional and specific focus on changes that we could make, near-term changes and longer-term changes to the advancing care information category.

So we had a request for information that went out last fall, we got a lot of comments on that, I will say an overwhelming number of comments certainly on meaningful use, which was incredibly helpful. And we have also, as I said, spent a great deal of time with the clinician community, both physicians and nurse practitioners and others to learn a little bit more about their experiences, what their pain points are and what they would like to see in the program.

So that was really our approach. I think our principles around advancing care information, again were to reduce burden and provide flexibility so that clinicians are able to get credit or rewards for using their EHRs in ways that are meaningful to them. Again sort of getting away from this all or nothing or one-size-fits-all approach to Meaningful Use that we've had in years past, to really focus on measures that are around interoperability or health information exchange. To allow, we wanted to actually have a design that would allow new participants to this category to be successful.

So while the proposals that we've made do propose to down weight this category to essentially zero, which is sort of the same as what we've done with exclusions under the current Meaningful Use Program, for certain types of clinicians like hospital-based or facility-based clinicians and nurse practitioners and so forth, at least for the first year. We are very interested in comments from the public and ideas about how and whether these types of clinicians should be included in this category in future years.

And those types of clinicians again, nurse practitioners, physical sorry...physician assistants, non-patient facing clinicians like pathologists and facility-based clinicians currently do not participate in the Meaningful Use Program, and we have proposed that the category for advancing care information would be down weighted for those clinicians, at least for the first year. And we have that flexibility, by the way, for any of these categories; if there are not measures that are available for a particular type of clinician, that that category gets down weighted to zero and is made up in some other category, likely would be made up in quality, because that's where you have the most metrics for the most specialty types.

So...and again, I think also really trying to focus on metrics not only of interoperability but that really promoted patient engagement as well. So looking at the this slide, it sort of shows you changes from the current EHR Incentive Program to advancing care information under the current Meaningful Use Program; again as I mentioned, sort of a one-size-fits-all, every objective has to be reported and is weighted equally. We really tried to make it as customizable as possible where clinicians can choose which categories to emphasize in their scoring, and I'll talk to the scoring in just a minute to show how that can be done.

We do require across-the-board levels of achievement or thresholds, regardless of practice type. This I think has been, from what we've been hearing, particularly problematic for certain types of clinicians;

particularly I think specialists have found this very problematic for every single category. So we really wanted to provide some flexibility and allow for diverse reporting that matches a clinician's experience.

The measures that have been in the Meaningful Use Program, I think for the most part up until the measures that we really have...did finalize for Stage 3 really do emphasize processes and the current measures still are somewhat process-oriented. But we again, wanted to focus on measures related to interoperability and patient engagement and there's a really strong desire from what we've been hearing from the clinician community to get to measures that reflect outcomes, with patient outcomes of care that have a relationship to use of electronic...or health IT.

The other thing that I think was very difficult about the, well it's actually still the current state; I sort of...I've already like forgotten about PQRS and value modifier, all I can think about is MACRA, but actually that's still in play, is that, you know, as much as we have tried to align in particular the quality reporting across PQRS value modifier and the current Meaningful Use Program, you know, if you use an EHR to report your quality measures and you have measures to do that and you can do that, that's great you really do only have to report once.

But that's just not a reality for everybody to be able to do. And so clinicians really do end up reporting twice for these programs. Your know through their EHR's to meet the EHR or the Meaningful Use requirements and then either by claims or through a registry, a qualified clinical data registry or the GPRO web interface or what have you, for PQRS and value modifiers. So that as definitely been problematic.

So one of the things we were able to do was really take the quality piece of meaningful use and just truly move it into the quality category and just provide extra incentives for reporting electronically; whether it be you know a certain number of the sort of 64 measures that you're using electronic data sources for reporting quality and give you extra credit for that. So that is that...the quality reporting piece has been pulled out of the advancing care information category and where it belongs really in, or where we think it belongs, you'll have to tell us we got it right, into the quality reporting category.

And then under advancing care information, there really weren't any exemptions for reporting. I mean there were hardship exceptions and that sort of thing, but again we have exemptions for reporting as I mentioned before, for the entirety of the program around folks who are in advanced alternative payment models, they still have to be using CEHRT, it's the reporting of it that is different there; folks who are in their first year of Medicare or who have low Medicare volumes.

So what determines the composite score under MIPS? Four categories as I mentioned before; one other thing to note about the advancing care information category is that Congress allows for us to down weight this category to 15%, no lower than 15% of the total MIPS composite performance score once 75% of MIPS clinicians are meeting the definition of meaningful use essentially. Under the current Meaningful Use Program, I believe around 74% of clinicians are meaningful users and so obviously we're close to that. The first year of the program we have proposed that that this category be weighted at 25%, which again is the weight that is in the law.

I don't think I have a slide with all the weights so I'll just tell you quickly. For the first year of the program quality is rated at 50%, resource use or cost measures are weighted at 10%, advancing care information is weighted at 25% and clinical practice improvement activities is weighted at 15%. The second year

resource use goes up to 15% and quality goes down to 45. And the third year and from there on out, both quality and resource use are weighted at 30%. And again, this is what's defined in statute.

So again for the advancing care information and this is actually true across all performance categories, MIPS eligible clinicians are able to participate both as an individual or they can participate in a group; that has not traditionally been the case for Meaningful Use that clinicians can participate as a group. We had the ability to do batch reporting, but really to actually report as a group practice has not really been a reality, but is what we have proposed. And again, you know MIPS is a whole, it is a sum of quality resource use, practice improvement and EHR use and so clini...what we're proposing is that clinicians report sort of as that whole, either as an individual or as a group practice.

I'm not going to walk through each of these; these are the six advancing care information performance categories. We have made a proposal to remove the reporting of performance on clinical decision support and computerized provider order entry; those are measures that are topped out, essentially. And again in an effort to reduce burden, we are proposing not to require the reporting on those categories. Of course those functionalities are still very much a part of 2015 edition certification upon which ACI, advancing care information is based. And so it is still a requirement for certification, but we are just proposing not to require clinicians to report that to us.

Computing the composite performance score; so what we did here, there's a lot of detail underneath this so I'm just going to talk about it at kind of a high level. We looked at all of our current value-based purchasing programs and how we score clinicians or other types of providers like hospitals and really tried to take from what we learned from our experience in other value-based purchasing programs for how we design the scoring methodology. But essentially, I'll just walk through each of our proposals here.

So under quality, we are proposing to require six measures, so that's down from the nine that are currently part of the existing program; so six quality measures. We do, instead of requiring that clinicians report across National Quality Strategy domains, so currently clinicians have to report nine measures across three National Quality Strategy domains, you know our goal in having that policy in the current programs was really to incentivize clinicians to report beyond just clinical process measures; understanding clinical process measures have value and that that is necessary for reporting. But we really wanted to incentivize additional types of measures, which was the purpose behind requiring the reporting of the National Quality Strategy domains.

What we learned and what we heard is that National Quality Strategy domains is very inside the Beltway it is not really something that clinicians on the front lines in their practices really understand or have meaning for them. And so in order to get to the same policy goal of getting clinicians to move to sort of broaden the portfolio from just clinical process measures to outcome measures, patient experience, appropriate use, safety et cetera, what we're doing instead is we are providing extra incentives or bonus points if you will, for clinicians to report these kinds of measures.

So you get two extra bonus points if you report and outcome or a patient-reported outcome measure and you get one extra bonus point if you report other types of high-value measures such as appropriate use measures, care coordination and a few others. So really just trying to provide extra incentives. We do cap the amount of the score that can be based upon bonus points at, I think we proposed it at 10%; I'm not exactly sure. But that was one of the things we did. The other thing that we did was we also

provide extra bonus points if measures are reported electronically as well. Each measure is scored on a 1 to 10 point scale and is compared to an historical benchmark, if there is a benchmark...an historical benchmark that is available. Obviously there will be benchmarks set for each of the measures.

Resource use is done very similarly to quality. We have our currently resource use measures that are used in the value-modifier that do tend to be more primary care focused. We also though have proposed over 40 additional episode-based payment measures that have been part of our feedback reports that we've made available to clinicians over the past few years as part of the quality and resource use source report requirements. So these have been in play and clinicians have gotten feedback on them, but we haven't used them as part of a payment program to date; so we are proposing to do that.

And then under advancing care information, again remember I said that we really wanted to not only make it flexible and allow clinicians to choose measures that are most meaningful to them and their practice to really emphasize their performance on those measures. We also wanted to set up a system whereby new entrants into the program had an opportunity to be successful. So what we've done is we've sort of if you think about the advancing care information on the 100 point scale, to meet...and is weighted at 25%, what we've said is, okay 50% of your score, we're calling the base score. And think about that as sort of pay for reporting. So if you just report to us, and you have to report something on all six of the objectives, that you get 50% of your score,

And then your other 50% to get to 100, you're able to customize based upon the measures that you want to emphasize. So...and so there are multiple pathways to get to a higher score, depending upon which measures that you want to emphasize; so that other 50% is sort of based on performance, if you will, and so how, you know what your percentages are on each of those metrics. And so there's a total cap of 100 points. If you add up all the metrics it actually goes to 130 points, but it's kind of like high school where if you like score over 100, you still get 100 right, you don't get 120, you get 100. So it's still, the cap really is 100,

So, and we really tried to unify the scoring system across all four of the categories. I will say that advancing care information is different from the others; while each of the measures is on a 10 point scale, because we have this base in performance method that is a little bit different from the other categories. So again, seeking comment from you all and the public on whether or not this makes sense or whether or not there is a better way to do this.

Okay, almost done. So data submission for MIPS; I'm not going to walk through every single one here, but this is really...these next two slides we just want to demonstrate that one of our other policy goals was to find ways that clinicians could use a single way, a single method to submit data for all four categories. Because currently, you know there's a couple of different ways clinicians are going through two or three different avenues to report information to us and that's just too burdensome.

So we wanted to at least allow for the possibility or have a provision that clinicians can report through a single entryway. So if you're using a QCDR that is working with your EHR vendor to report on your quality metrics, your advance...your use of certified EHR technology as well as your clinical practice improvement activities, and that's just one pathway for you.

Resource use, by the way, is all claims-based, so that's done by us. We...these measures are based upon

administrative claims, they are risk adjusted and so that is no burden for clinicians in terms of what they have to do to actually report. So these slides are really just to show that we have multiple methods that really align across each of the categories. I will anticipate one question that we've gotten before, which is around clinical practice improvement activities, on the next slide, slide 27. We do have administrative claims as a method to reporting there; we actually don't have a current clinical practice improvement activity that we have defined that would use administrative claims; we wanted to at least allow for the possibility if one were proposed to us that could be captured using data on administrative claims. So again, we're trying to be inclusive here to allow people to again have sort of a single mechanism to report on at least three of the four categories, again with resource use being done by CMS.

So the performance period; so all four of the MIPS categories are aligned to a performance period of one full calendar year, and it goes into effect in the first year. We have a proposed that 2017 be the performance period to affect 2019 payments. I don't think this was a surprise to anybody that we proposed this. And, you know, we've certainly gotten a lot of feedback from clinicians and others that they would like the performance year to be closer to the payment year, which certainly is a very reasonable desire to have.

I think some of the challenges, just to be very clear about what those challenges are is, you know if you think about all of the steps between the performance and then the payment, there's a lot of them and I think we have work to do not just internally at CMS, but certainly internally, but also with our clinician stakeholders on how we can narrow that window. Because, you know we propose a year-long performance, partly that's because most measures are defined upon 365 days, but also, you know we used to have a six month reporting period in PQRS that was optional, for people to choose and 0.5% of clinicians chose that option.

And what we always heard was that that was a less desirable option because measures just weren't reliable with six months of data and people wanted a years' worth of data. So that's why we have traditionally had a year-long performance period. But certainly, you know, open to alternative ideas on that. Then you need about three to four months to actually report, and we almost always end up extending, because people feel like they need more time to report. So I think as that gets more streamlined, that's an area where we may be able to reduce that time period, especially if we can get to a place where reporting really is just part of the work flow and not an extra activity.

And then you need time of course to do calculation of all of the measures and then to determine the payment adjustments for clinicians. And then we have to give feedback reports and then...because we want clinicians to see their performance before they choose what it is they want to do in the following year in terms of the way they want to report the measures they want to choose, etcetera. So you start adding up all of that time and then you've gotten pretty close already to the payment year.

So I only say that to be transparent about why we have the performance year separated from the payment year by a year; but again, we understand the very strong desire to have those be closer together and are very willing to work with the clinician community and others to figure out how we can do that over time. But we did not feel we were going to be able to do that in the first year.

So putting it all together, if I can get this...there we go. Okay, so what this slide does is it looks at the years 2016 through 2026 and how the...with the fee schedule updates first is on the top line there; so fee schedule basically is at 0.5% each year, and this is all by the way of course in statute, between 2016

and 2019. Starting in 2020 there is no change in the physician fee schedule, it's all based upon the multiplier up or down from MIPS, as well as participation in advanced APMs. And then starting in 2026, as I mentioned before, eligible clinicians who are part of MIPS get a 0.25% update each year in addition to the MIPS multiplier of 9%. Or if they are in an advanced APM and they are a qualified participant, they get a 0.75% update.

For MIPS the adjustments go between -4% and +4%; so the maximum downward is a -4%, but we know that people are going to fall on a scale between -4 and +4. One thing to be very clear about this, that you all probably know but I want to be sure I'm clear about it is that this is a budget neutral program by statute. It is a budget neutral program, so that comes with all of the implications there.

And so one of the things the law does, it allows us to apply what's called a scaling factor to the upward adjustment in order to meet budget neutrality. So those who fall between zero and -4% essentially will be the pot of money that funds those who get an upward adjustment between zero and 4%, again in the first year. And again, that could potentially scale higher.

I also want to mention that there is \$500 million years a year for the next six years to provide extra incentives for very high-performance under MIPS, so we have made some proposals there as well. And then, of course, for folks who are a qualified participant in advanced APM, you get the 5% bonus each year for 2019 through 2024.

And I'm not going to read this is slide, but this basically is information for you about how to submit comments. We are eagerly awaiting comments. I would ask that, please don't everybody send your comments on the very last day, but we know that'll probably be what happens, because people need time. It's a lot to digest, but we are doing a lot of engagements between now and then with entities such as this one, but also a number of organizations. Anybody who wants to talk to us, we want to talk to them, although we do need to kind of figure out a way to organize that, because we only have so much bandwidth. Because it is really, really helpful to us to hear your comments in person; whatever it is you're going to put in your letter, so that we can start thinking about that early.

We don't have a huge amount of time between the end of the public comment period and when we have to get the final rule out. Our goal is to get the final rule out in early fall, so like end of September, early October; we have until November 1, we would like to get it out sooner than that so the people can have a little bit more certainty, with a little bit more time to prepare. And about preparations, the last thing I'll say, but we get asked a lot you know, how do I prepare for MIPS? Well remember, MIPS and APMs are holding clinicians accountable for the same things we hold clinicians accountable for now quality, cost, use of EHRs; of course there is a new category, clinical practice improvement activities. So the best way to prepare is to participate in the current program, because yes, they still do exist in 2016; so PQRS, Meaningful Use and the value modifier. That is absolutely the best way to prepare for MIPS.

And so I will stop there; I know that's a ton of information. We actually have a 96 slide slide-deck on our website that is outstanding. And so anybody can go and use the slides in your own presentations or for your own use; we encourage you to do that and so that's available for you as well. So, I will stop.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thanks Kate. Very thorough and it does take repeated listening, reading to digest this all. So let me maybe open up with common question. So clearly you've been extremely responsive to all that you've

heard. That does create both flexibility, but also complexity. So one question, I'm sure you're asking us to comment on what ways could we simplify things. Another is, we had the REC Program in Meaningful Use that would help especially the primary care and especially rural. Is there something like that, in a sense, to help people get through this or even the people who help people get through this to improve the understanding?

Kate Goodrich, MD, MHS – Director, Quality Measurement and Value-Based Incentives Group, CCSQ – Centers for Medicare & Medicaid Services

So yes, there is a lot of help out there; so let me walk through a few things. The MACRA legislation did provide \$20 million a year for five years, so a total of \$100 million for us to provide technical ass...or to contract with entities such as RECs, regional health collaboratives and QIOs to provide assistance to rural and small providers specifically. So it is very focused on that.

So we have put out not to be RFP yet, but we've put out the initial notice publicly, I think a couple of weeks ago. The actual proposal, request for proposal should be coming out really soon and so we're excited about that. That is a super high priority because, you know there's been a lot in the press about this, but I will just also say internally what we worry about are the small practices and the individual practitioners and the rural providers, and that is what we worry about. And we want to be able to provide as much assistance to them, but we also know there's a lot of surrogates out there who are able and willing and want to provide assistance to them as well. So that's number one.

Number two, we have a Transforming Clinical Practice Initiative which is very large scale, almost \$800 million initiative that originally was focused on helping providers being successful in the value modifier, but obviously that has transitioned because now we have MACRA. So tho...we awarded dollars to 26 Practice Transformation Networks, I think it was 26 and 10 Support and Alignment Networks, who are in the process right now of not only recruiting practices, but also to do practice assessment to see where they are in their potential transformation. And the goal is to help these practices, and by the way it's all over the country, be successful in MIPS and have the ability to redesign their practice and basically give them, you know frontline help on how to transform their practice to be successful under alternative payment arrangements. So that's number two.

Now that of course doesn't cover everybody out there...oh, and then number three actually is the QIOs; we actually do have a task within our QIO statement of work directly related to helping providers be successful under, well it was again the value modifier. And we've worked hard to make sure these things are all coordinated and don't overlap one another; that's been a very strong focus for us.

We also know though, there's a lot of what we're sort of calling surrogates out there, I would include registries and EHR vendors and specialty societies and lots of other folks who have a great interest in helping clinicians be successful, but also clinicians are asking them how to be successful. You know one of the things you all know well that I've been hearing since I was working in this field at CMS is a lot of clinicians look to their EHR vendor for what to do for not only Meaningful Use but for PQRS.

And so I don't think that's going to change, I think that that's just who clinicians work with and now more and more registries as well and so we feel like it's really important to equip those surrogates just as much as anybody else with the information that that they need to be able to help those providers. And so it's not just giving them the information on telling them exactly what they need to do, but also where else they can go for help to get more of that sort of again, sort of frontline help.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you very much. We have certainly a number of questions and I'll start at the very end, whose card's up?

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Elise.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Elise, go ahead.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

...you know everything, what's your question?

Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So, one...I know, well one I just want to say thank you first on behalf of ONC. I think CMS and ONC worked very closely, as we did in previous rules, MU and so forth, to really think about the health information technology requirements that flow throughout the rule. So I want to just show appreciation for all of the work that you've done across CMS to really think about that, as well as folks like at CMMI and so forth that think about it as it relates to the alternative payment models as well. So a couple of things I wanted to highlight or kind of build-on from Kate's presentation.

One, the 2015 edition of the foundation; I just want to emphasize that because the same way Kate gets a lot of questions on how to prepare for the upcoming year, I think this is a very important concept that as we were working with CMS and thinking about that the requirements for, I'm going to try not to use acronyms, the advanced care information category as well as across APMs that we thought about the 2015 edition and that is the foundation. So thinking about the requirements, there are developers who are now getting ready to come in to be certified, that 2015 edition will be the basis for what is included in the final rule. So I just wanted to note that.

A couple of other components; because CEHRT kind of flows not only on the MIPS side, but also on the APM side, when Congress put together the law, they included a provision on information blocking and it's an attestation. And that's also in the rule, it's actually the only, if not the only provision that doesn't just refer to the eligible clinicians covered by the Quality Payment Program, but also includes hospitals, critical access hospitals and those EPs that are not covered under the Medicare side, so like Medicaid EPs for example. And that was what Congress included in the rule, so you'll see a provision that captures that in the rule is the information blocking attestation.

And a corollary attestation is included on surveillance, so part of the concept being, use of certified EHR technology and the ability to exchange using that depends upon information flowing appropriately when and where it is needed. And that's what's articulated in the components for the information blocking attestation. The other component is the surveillance side, so to be able to make sure that the technology being used by these providers is doing what it's supposed to do, we want to be able to surveil the product and see that that's happening. So there are two attestations that are included in the

rule. So I just would like folks as well look at those and we welcome comments on those provisions as well.

This was noted by Paul as well as Kate, so I'll just mention it now as well that the FACA will be looking at MACRA as a rule and we're focusing of course on the health information technology component. That will be coming up soon, so please look forward to...we look forward to your input on that, particularly the public comments as well, we would love for people to participate in those workgroup sessions.

Related to that, that's going to be a very quick timeline obviously because we want to get comments back to CMS as quickly as possible. And to Kate's point that this is the first kind of iteration of MACRA, we do anticipate that there will be additional opportunities for us to examine some of the more nuanced points in the future related to the MACRA and Quality Payment Program landscape. Initially we're focusing on some of the larger concepts and we've been working with CMS to develop a charge that kind of captures those core components. So we really look forward to working with Paul and others as we look at that; so look forward to that coming up next week I think is hopefully when we will start that endeavor and it will be kind of moving fast and heavy at that point.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Good, thank you. Richard?

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So first of all thank you for the presentation; it's a very complex topic and I think you did a good job of explaining it. I think it's clear that CMS and ONC did listen to a lot of the public feedback on the individual elements which were simplified. I would still note that when you look at it in its totality there's a great deal of complexity to this.

And my questions to you are related to kind of, how do you think providers are going to respond? I'm concerned that small provider organizations, small providers are going to be unable...it wouldn't be manageable for them, so I was wondering if you've been thinking about that and what your thoughts are. Patient centered medical home is limited to a pilot, so they're option...optionality through CPC plus is limited to a pilot perspective, so you know kind of what are their paths to be able to participate in this? So that's one question is kind of what happens to the small provider?

Second question is, it sounds logical that providers start out primarily in MIPS but then as they look at MIPS and they see the, kind of the 50% downside, does that kind of force a large migration towards APM and is there any thought about what is going to...what directionally is going to happen to providers over time as these programs go into play? So, appreciate your thoughts on that.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Just one point of clarification, you said a 50% downside, I'm not sure I understand then.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So, the...so just the way the incentives work under MIPS, there's more...if you're in the top 50% you have the potential to benefit from that whereas if you're not in the top 50%, you do not...

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

I gotcha, I got it.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

...and that may create some setups for migration to the APM program. What I'm trying to understand is what your thoughts are about how do you think providers are going to respond to the rule?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Sure, okay, let's start with the first question about how clinicians are responding and particularly the concern around small practices? So we've been out on the road, if you will, speaking to a lot of clinicians I've been hearing some responses. Right now I think people really are still digesting, absorbing so most folks have not fully absorbed what's in the regulation. And again, initial response is what you've said, which is of course true, which is the complexity and it is a complex law and it is a complex rule. And one of the things we definitely want comment on are where are there areas we can simplify? And we worry about that in large part because of the small practices.

So I think a couple of things there; there are a number of provisions in the proposal that we made for everybody, but with small practices in mind. One of those had...part of that had to do with reducing the number of measures, reducing the burden on what it is that people have to report. Also for practices, I think's 15 or fewer, they can report on fewer numbers of clinical practice improvement activities to get full credit, for example. And then of course we have all of the technical assistance that we're providing for small practices.

However even with all of that, we definitely feel like this is a population of clinicians that we really need to focus on, not just in terms of our policies but in how we help them to understand what it is that they have to do, that we and other surrogates help them understand what it is they have to do. Because undoubtedly it's going to be overwhelming to sort of see all of this.

So some of you have heard me talk a little bit about the approach we're taking in how we interface with clinicians as we are developing the policies, the IT systems, the communications and so forth. So we are very focused on developing content in communication that is really focused on small practices and individual practitioners, very much with them in the mind and actually have, you know tested out with them so we can understand what actually works in terms of explaining all of this. And that's going to be ongoing, by the way, that's not, you know a one and done kind of thing, so I think that's part of it.

Under CPC you mentioned the CPC plus and this is where maybe I'll Patrice or JP to weigh in. One thing to say about it though is that the idea behind CPC plus is to recruit practices that are small practices and I believe that, and here Patrice I'll need your help, that clinicians that are in practices I think of 50 or fewer are the ones that are going to be eligible, and I may be conflating this with medical homes, eligible for the APM incentive. But let me see if I can ask Patrice or JP if you are able to answer this question about sort of how CPC is going to work for small practices?

JP Sharp, JD, MPH – CMS Innovation Center MACRA Lead – Centers for Medicare & Medicaid Services

Sure, can you hear me Kate?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yes, thank you JP.

JP Sharp, JD, MPH – CMS Innovation Center MACRA Lead – Centers for Medicare & Medicaid Services

Okay great, yeah, this is JP. So I think that CPC plus represents, you know as was stated, it's a pilot program or demonstration, but the law provided the avenue for expanded medical home models to be a longer-term avenue to get to that advanced APM status. So really the goal for CPC plus and all other models at the CMS Innovation Center are to meet those expansion criteria of reducing costs and/or improving quality so that we can get to that expansion phase, make it a longer-term larger program that's available for more and more practices.

And yes on the 50 or fewer point, that's also correct as proposed that advanced APM status would be specifically targeted to practices with 50 or fewer eligible clinicians in their organization.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Thank you, JP. And then getting to your second question around sort of the budget neutral nature of MIPS and at that 50% will get a negative payment adjustment, so...and will that drive people into APMs? I think the law was designed to move more and more clinicians into alternative payment arrangements and specifically provided for incentives in a few different ways in order to do that. What I will say is a couple of other things.

Number one, we really tried to design MIPS in a way that would prepare clinicians to be successful in APMs and be able to, you know move them to be able to accept downside risk and be under these alternative payment arrangements. Keep in mind that clinicians who are in MIPS are actually really held accountable for the same kinds of things as clinicians in APMs, right? It's quality, cost, improvement, and use of EHRs, so we really wanted that for clinicians who want to move into APMs to allow that transition to make...help them to be ready for that.

And then the second thing I'll add though is while MIPS I think can be a good on-ramp to folks who want to move into alternative payment models, I think there is a reality that for some clinicians, particularly high performing clinicians, that MIPS maybe actually be the avenue that they want to stay in. Because there is a potential for higher upside in MIPS in the 5% bonus. Now that, I think people are going to have to experience the program to understand what is best for them and where their performance is, but we think that that actually is going to be an outcome for some clinicians that they choose to stay within the MIPS program, but we'll have to see.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you very much, just one closing comment. I think it would be good for CMS to collaborate with organizations that can help with educational outreach. I think that this is a program that really needs to be understood, even to collect public feedback.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yup.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And I know a number of organizations represented around this table are trying to decide if we can just encourage the CMS group to collaborate, I think that will be helpful as well.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Thank you, yes agree.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Okay, we have a number of questions, we only have 13 minutes left so if everyone could just one question and try to shorten up the questions; thank you. Floyd.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC

All right, I'll limit to one. So I know there's been a lot of work on measures and many are process measures that get redone every year. So question on the measures for those...what kind of activities are you doing to increase outcome measures in the set? And for those who use registries, many registries are requiring manual entry because they don't trust the EHR information, so how does that address use of the EHR if they report to registries?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yup, so on the first question, if you look at our portfolio of measures, it is definitely more balanced than it has been in recent years; there are more outcome measures and more appropriate use measures. It is still more process measure heavy that is true, that is mostly what is out there and particularly for electronic measures, that's just easier to do. So, but it is changing. I will say many of the specialty societies have gotten very engaged in measure development and I think have heard from us and other commercial payers about our desire to move to outcome measures as much as possible and have heard that they're actually acting on it.

So I've been very pleased by what I've seen come our way; I've really seen a shift in the last couple of years. So I invite you to look at the portfolio, it's definitely changed some over the last few years. And of course we have \$15 million a year for CMS to work with specialists and others, who are measure developers to develop measures to fill gaps, and the law very, very explicitly focuses on outcome; patient reported outcome, appropriate use and so forth.

So we're excited about that opportunity. We released our final measure development plan around May 1 and we have been doing a lot of stakeholder sessions, some of which you all...some of you may have been involved in, to listen to what are some new and innovative ways we can go about developing measures? I think we really want to think about what's the next generation of measure development to sort of get to that place where it's more rapid cycle and it's a byproduct of work, right?

And so your second question, we are aware certainly that some QCDRs and traditional registries are not truly using electronic data. So we do work individually with the QCDRs and we set parameters around...and will be setting parameters around what exactly that means. I'm not technically enough in the weeds to tell you that, but we are certainly aware that that's happening. And I think as we move forward on sort of this next generation of how we capture electronic data and how we build measures

off of that data, and where flows in a much more liquid fashion than it traditionally has, that's not something that we at CMS are going to be designing and figuring out how to do alone.

I think we have to work, and we are working very closely with a lot of people who are much more experienced in this realm and that would absolutely include the registries and the vendors to help us solve that problem. That problem isn't going to be solved from Baltimore; it has to happen as a community, I think.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Great, thank you. Eric?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

I had a question about quality reporting under MIPS. It wasn't entirely clear to me whether the payment received would depend on the actual measured quality or simply on whether or not the quality measure was submitted. Can you clarify that?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

It is based on the performance, the clinician's performance or the group practices' performance on those measures.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

Thank you.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you. Leslie?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes thanks, I have one question and three comments. So I'll start with the comments; is it would be wonderful to see a part of CMS initiatives to have an ideal clinic pilot because I think that part of this is it's a moving target, folks don't understand it, they don't know what "it" is so having an opportunity to see what that clinic would look like would be helpful. Also telehealth more broadly defined and harmonized across all of these initiatives would be helpful; they mean different things in different places.

And the third comment is that you mentioned that CDS is topped out; it's really just starting when the patients are considered part of decision-making. And so the certified edition allows for patient participation in shared-decision making and CDS and has not had any measurement there. So I think there's...it's not topped off with all participants.

And then my question is, how are we going to harmonize the standards under certified with different cadences of MU going away, with MACRA and MIPS coming in with standards requirements that may flow at different times and needs and that those standards will have to evolve. What are your thoughts there?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

I'll give you my initial thoughts which are very uninformed about standards, not my area of expertise and I may ask others from ONC to weigh in on this. I mean, this is one of the reasons that we do work so closely with ONC, which is where the expertise on standards related to, you know, not just quality measures, but every part of the work has to happen. So that partnership with ONC, obviously long history there but has been part of the discussion as we transition from what will soon be the legacy programs into MIPS, but I will ask if Elise or anybody else wants to add to that?

Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So when I was saying, I actually neglected to mention this, I was going to so perfect segue, thank you Leslie. For 2017 it's actually a flex year so some might remember in the past where we provided a flexibility year so that folks would have an opportunity to kind of transition from a previous edition of certification criteria over to the upcoming edition. So that happened in the past and that's the same concept that you'll see in MACRA for the 2017 year.

So it's kind of come as you are for the 2017 year, and obviously I'm simplifying that tremendously, but that's the concept. So that you could use 2014 edition and there are certain requirements attached to that, you can use a combo of 2014 and 2015 or you could use 2015 edition and there are certain corollaries there. But you can see that already we're thinking about how to make sure that transitions are able to happen as standards are updated and innovation is happening.

And I would just point as an overarching concept, in past years or past Meaningful Use rules, we...there was always a kind of coordination between CMS and ONC in terms of getting ready for the next edition that ONC was getting ready to release and I think the same thing would exist here that we would continue to work with CMS for future editions that may be released. The timing of 2015 is actually really good in terms of we're givi...we...folks can come now to be certified, use it now and then be ready in 2017 to do that. Or, if there's a little bit work to be done and they have some modules that are 2015, but not...the whole system hasn't been upgraded, then they can use a combo.

We also think it's good for developers as well so it provides an opportunity for potential stagger...making sure that you're all of the providers that you are covering can have what they need by the 2018 year, but really provides an opportunity for the 2017 year to be used as well. So there's some flexibility in there and I think that's the start of it and then for the future, absolutely encourage public comment on this, but there would be coordination...continued coordination between CMS and ONC. Does that answer your question?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yes, thank you.

Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

Wonderful, okay.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you. Troy?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

Thank you very much. So as you were going through this, I'm pleased to hear that this truly is incentivizing the continued use of EHRs in a much better way...

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

I know, I can...

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

...yeah. Umm, you know as I reflect back, I was thinking about ARRA and the initial stimulus funds that came out and we often talked about the carrot and the stick; you know initially we had of lots of carrots, you know the incentivization of EHRs and Meaningful Use, but we reached a certain point in time where the stick came into play, so we started looking at payment adjustments for those that decided not to use EHRs and become...come into the program and utilize the system. Has that program, now that MACRA has come in and this is more of a global but, has that stick, has it gone away, has it been dissolved now with the MACRA proposal and the further incentivizing of using advanced payment models and MIPS?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Mm-hmm. So the payment adjustments, which is the stick part of Meaningful Use ends in 2018, at the end of 2018 because the first payment adjustment up or down for MIPS begins in January 1, 2019. So I guess you can think about...that's just how the law is written so I guess yes, that stick does go away and it does get folded in sort of to the totality of MIPS. And by the way, because there isn't an incentive to get people to adopt EHRs anymore, by the time you have MIPS come around and of course I think this is the last year for that anyway, umm that was the other reason that we designed the advancing care information category the way that we did was again to try to have it set as a bar that we thought people could mostly achieve but had an opportunity to do really well in, you know to the extent that they could.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

All right; thank you.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

And just to be clear, the incentives whether they're up or down for Medicaid and for hospitals are unchanged.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

Okay.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

This is really about Medicare clinicians is what MIPS is about.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

One more clarifying...can I ask one more? Okay. Are there any sticks that are foreseen in the MACRA program, because I haven't heard of any...

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Any sticks for what, I'm sorry?

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

Are there any negatives or any sticks or payment adjustments that are associated with MACRA, MIPS and AP?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

As a totality of the program, and it's all based upon performance, so it...right? So if you are a clinician and you know, you're composite performance score across all four of those categories falls below the threshold that we have to define, then that is a downward, I guess you can call that a stick, that is a downward payment adjustment. But it is purely based upon your performance in all of those categories whereas under Meaningful Use it was you adopted or you didn't, right? You adopted and you met Meaningful Use or you didn't adopt or you adopted and you didn't meet Meaningful Use and it was kind of, you know more binary. It's not that way in MIPS at all; it's really about totality of performance.

Troy Seagondollar, RN-BC, MSN, UNAC/UHCP – Regional Technology Nursing Liaison – Informatics Nurse – Kaiser Permanente

Okay.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you. Kathy?

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Thank you. So just two comments, maybe one is a follow-up. I think that the relevant slide from Kate's presentation is the one that shows the arrows, some going up, some going down below the zero point and I think that that does show where there are both shall we say carrots as well as sticks.

My question had to do with planning for next year and certainly appreciate the mention of the qualified clinical data registries. The list of approved for use in 2016 clinical data...qualified clinical data registries only came out on May 6 and so what happens then to clinicians who are using registries as their platforms for submitting measures, for indicating that they're doing practice improvement activities, umm that they're participating in electronic health records systems and then find out on May 6, 2017, oh my goodness, my qualified clinical data registry that I have put all of my eggs in that basket maybe got disqualified or ended up, unfortunately through no action of my own not having a sufficient number of measures. What happens to the participants at that point?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah, that's a great question. So we need to...we've talked a little bit about this internally and I'll take this back to my team and maybe get back to you with sort of an answer related to timelines, because we know that that's too late for a lot of folks, for most folks to know. Because most qualified clinical data registries we would anticipate, although it's not guaranteed would be...if they're qualified one year will continue to be qualified. But of course that's not ever guaranteed, but we would hope that that would happen.

So we need to get to a place we're able to, in advance of a year, instead of during a performance year, be able to announce what the QCDRs are and the traditional registries as well. And I know the team is working on that, I don't have a specific answer for you, but we understand the issue, definitely. So maybe I can come back to you with more on that later.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Because I think that maybe one area, just as follow-up, one area in which the ability to then switch or do partial year reporting, if you've been reporting through a registry thinking it will be accepted then lose that option, you have to pivot very quickly to something else.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yup, that makes sense.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Thanks.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Good, thanks. Arien?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I will refrain from commenting on advanced APMs and the definition of risk. So first of all, my understanding for the advancing care information performance category, and correct me if I've got this wrong, is that the protect patient health category is mandatory and if you answer that no, you are effectively zeroed out for the rest and that that requires you to do a risk assessment and other activities related for that; so I want to clarify that point.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

That's right. Yup.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

The question that I have is, could you walk me through what will be required in 2017 and what is new in 2017 to establish the performance period, assuming that I'm already a meaningful user and participating in PQRS? So maybe walk me through what's different or not different in the Meaningful Use and PQRS programs relative to the MIPS program and then how I would qualify for the CPIA? I would assume that

the VBM versus a cost category is done administratively, I don't need to worry about it so it's about CPIA and what might be different in Meaningful Use and PQRS relative to their equivalents in MIPS.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yup. So if you go online you look at our slide deck, we actually have a couple of slides that show that explicitly, so I should have included those, but I'll tell you. Let me start with resource use. So you're right, that is done administratively and there is an attribution methodology that would attribute you as a clinician to particular measures and we only use the measures, by the way, as part of the calculation; if you have a minimum case size that meets reliability threshold, just to say that out loud.

For quality, the differences are that instead of nine measures across three domains you have to pick six measures. One of those does need to be an outcome measure, but if there's not an outcome measure that's available to you, you can instead choose another what we call high-value measure, if one's available for your field of practice, your specialty. So...and then you also will have the ability, so you should look ahead at all the measures to again potentially score more points, and this is just extra bonus points; it's not like we're ex...double-weighting the measures or anything, but extra bonus points the more sort of high-value measures that you report. So that's the big difference in quality and the domain requirement is gone but again, extra incentives for higher value measures.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Sorry, just to clarify that, do you expect that the measures that most people have picked for PQRS will also qualify for the six, including one outcome measure or do you expect that most people will have to change the list of measures that they'll be looking at?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

No, I think it's going to be very similar. We do have some new measures that are proposed, because we've...there's been more measure development that we and specialty societies have done. But the list of measures that is in the regulation, the proposed regulation is primarily the PQRS portfolio of measures. Now remember, measures that are part of the QCDR don't have to go through notice and comment rulemaking; so if you're working with a QCDR, you can continue to use the measures on that QCDR, but the same rules do apply in terms of bonus points and so forth. Okay?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

For Meaningful Use, because advancing care information is wrapped in to one program now, it's not a separate thing, umm the requirement would be for reporting based upon the performance period, which is 2017, right, so for the calendar year. And so what we would advise folks is to look at the measures that ultimately would be left, assuming that we final...let's say we finalize what we propose, right? Then you're looking at six objectives and there are a certain number of measures under each of those. And again, you get 50% of your advancing care information score just for reporting, but then you can look at the other measures and what you think you're able to achieve on those and figure out if there's a pathway for you to get to 100 points based upon the measures that are there.

Now we understand that by providing that the flexibility that did add complexity. That is a perfect example of where trying to reduce burden and provide flexibility certainly does make things more complex. We are really focused on that and how we can talk about the that and provide information on that in an understandable way.

For clinical practice improvement activities, didn't exist before, new activity. What we're proposing for the first year is essentially an attestation. So we will have through our physician portal that we are working on now, which will be a single point of entry for the entire program that clinicians will attest to as many improvement activities as they are doing, based on an inventory of over 90 clinical practice improvement activities that are proposed.

We...by the way for that category, we not only went to specialty societies but also to high-performing organizations to understand what types of improvement activities people were engaged in. So for example, maintenance and certification part four is an activity on the list, because we know a lot of clinicians are doing that; but there's lots of others. And so that inventory is based upon what is actually happening out in the world now that has...either we have evidence of or maybe not evidence but people believe is leading to higher value care for clinicians.

So we tried to be fairly broad with that. But in any case, so clinicians have to, in order to get any credit in that category you have to attest to at least one. And this is an area where I think I mentioned before small and rural practices in order to get full credit need to attest to, in order to get all credit others would have to attest to at least three.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So a couple of follow-ups, just because I think this 2017 could be horrible or it could be just fine. So what I'm hearing you say is for PQRS most clinicians won't need to really do anything because the quality measures for MIPS will already be the quality measures for PQRS. For Meaningful Use, I was a little lost in your gives and takes...

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah, sorry.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

...your puts and takes. What I'd like to hear, and maybe this is not true, what I'd like to hear is my EHR that I'm already using and the way that I'm already reporting for Meaningful Use I don't have to change a thing for 2017 and CMS will just take care of the puts and takes?

Kate Goodrich, MD, MHS – Director, Center or Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah, that's really true actually. So, you know let's say we finalize you don't have to do CPOE and CDS; we actually do have an alternate proposal in there to keep those two in, by the way, so we...that's possible. But let's just say we finalize, based on public comment, to exclude those two then yes, you should just report whatever it is you are doing, you don't have to worry so much though about hitting a certain threshold, right? You just report whatever it is you're doing that makes sense to you for your practice, don't worry about those 80% thresholds or whatever they are, just report what makes sense. And if you just report, you're going to get half the score. And then we on the backend calculate the rest,

based on how you do on each measure. Does that make sense? It's probably a better way of actually saying it, thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

That's great, yeah, I'm really probing for areas where I've got to swap out my EHR technology or install something new or do something that's meaningful that's required and then for CIA it's more about going to website and doing attestation as a one-time activity.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah, and what we're doing is we're designing it so that you go in and you do your attestations for everything.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Right.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Thank you.

Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

You know, I think Kate'll move into this but just to say it frankly that the objectives and the measures or the measures that are included are really based upon the Stage 3 and Stage 2 modification measures.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah.

Elise Sweeney Anthony, Esq – Acting Director, Office of Policy – Office of the National Coordinator for Health Information Technology

So I think that might get a little bit to your question.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

The measures are the same, thank you for saying that, Elise; that's exactly right. So our goal was to not make people have to do something completely different and buy any new technology. That was our goal.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Perfect, thank you; that was the answer I was looking to hear.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you. Devin?

Devin M. Mann, MD, MS – Assistant Professor, Associate Chief Medical Information Officer for Innovation and Population Health – Boston University School of Medicine

Umm, pretty simple question. I was really excited to hear kind of this trying to be more agile, really listening to folks as you're developing these measures. I guess my question comes to then, you know as the program goes forward, and one of the stated goals which I totally agree with is trying to reduce burden. What gates are in place to check if that's happening early on, so that we're not in 2019 being burdened by something unanticipated?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Right, totally agree that that is possible, something we're not even thinking about now. So we have built our competency capacity, whatever you want to call it, within CMS within, you know across CMS to umm...around education outreach we'll use as sort of a catchall category. That includes communication, that includes technical assistance, to be a much larger machine in operation than we've ever had, particularly around MACRA or quality care program because, I think what we've learned already even though it hasn't...we've only been working on this for a year, right, is that that ongoing constant engagement, and I don't just mean like we have an open door forum, I mean we're actually in the practices with the docs, which we have been, has been incredibly powerful and has really informed what we're doing in a way that we've never, I think done before.

And so we are building that operational capacity to continue that as this program goes forward, because I agree with you, I don't think we can just learn a year after the reporting period what worked and what didn't, that's not going to make any sense. I think we have to learn like during the year as people are working on the program, even during the performance year, but certainly during the period of actual reporting as well.

So we are setting up processes to get that rapid cycle feedback, we've actually had a number of particularly actually small practices, but also large ones who have been very interested in sort of being, you know if you will sort of test sites for us, so that we can work with them in their practices to understand what's happening. I honestly think that's the way to figure it out is like we've got to actually be there and see what it is they're experiencing. It can't just be some white paper that gets written that we may or may not read or just based upon public comment or just based upon an open door forum where everybody has the floor.

It has to be us actually experiencing it. But, you know and continuing to hear from in all of the avenues that we have. So I don't know if that's a satisfying answer or not, but the point is we recognize that it's absolutely necessary and we're building that competency.

Devin M. Mann, MD, MS – Assistant Professor, Associate Chief Medical Information Officer for Innovation and Population Health – Boston University School of Medicine

No, I mean I think that's sort of the process that you would hope is being planned. I guess the follow-up to that is, you know at some point though, the people who aren't those test sites will probably want to know, you know if they're experiencing something, is there a plan kind of like at six months or certain gates where we're going to distribute that experience and whether or not we plan to change direction or not, at least let people know that that's happening.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

I think we have absolutely a principle around transparency of all this stuff. I don't know that we've thought about specific time intervals or milestones where we should distribute that information, I see no reason why we wouldn't distribute that information. So if you or others have thoughts about sort of what makes the most sense there, then we would be very open to hearing it.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you. Andy.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Hopefully this is brief. I notice because you've emphasized it a couple of times that you're continuing to collect administrative claims in an environment when everybody is on an advance payment model and they aren't actually billing you for anything like that, what will you then and why would you then not consider it a burden to produce those administrative claims?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

So the administrative claims piece is really under the MIPS program, right?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

So as people move into APMs and especially where you have APMs that are, for example population-based payments, so they're not really based upon submission of a claim through the fee-for-service system, then you know where we're capturing things like quality and so forth in other ways through EHRs and so forth.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Maybe I'm not understanding your question, I apologize.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Well so, I mean at some point you're going to admini...eliminate your apparatus for collecting administrative claims and everybody else's apparatus for producing them, right?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Mm-hmm. Right.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So is...ought there not to be...I guess the real question is, shouldn't there be a timetable for that? If everybody's shifting into APMs and away from all of this, because it is nonsense as we talked about, all of us times.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah, I don't know what the timeframe is, I mean and whether or not we ever get 100% for every clinician on the planet away from administra...billing through the fee-for-service system, that may happen, I don't know; you know certainly shifting in that direction. You know, if that were to happen then we would have a whole new system for how we pay clinicians and that is happening at CMS, right?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

That's where you're going, right?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

I mean that's actually...that's happening now, right. We're not getting rid of our fee-for-service system yet, because for some time that's going to need to be in place, but we are redesigning some of our systems for these new payment models as well.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

...that the resource use category, and Kate please correct me if I got this wrong, but the resource use category for providers who are participating in an APM, even if it's not an advanced APM would be the resource use...it would be the resource use category of the APM, not the administratively calculated resource use under MIPS.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Right.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So if you're participating in an APM you essentially delegate to the APM the resource use category; do I have that right, Kate?

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yeah, that's right. I mean, and if you're in an APM most APMs, you know they're held to some cost standard whether it's total cost of care or is a target price based upon a bundle or something like that. So that's really how that's how that's accounted for at the APM higher level.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Great, thanks. Lorraine.

Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health & Human Services

Thank you. Well the last two questions were not an intentional lead in, but I appreciate them. So I'm with the CMS, Kate and we had a discussion about our eHealth Collaborative Roadmap for working on this small thing called Title II under administrative simplification for HIPAA, which has to do with administrative transactions, namely one of them is claims and another one is prior authorization and how physicians are working with those and how they are getting educated about to them.

And so really it's more of a comment and/or suggestion that when we get back to our respective place at Security Boulevard we continue to have a conversation about how we work together collaboratively on the training and talking to the providers because if you're going out and working with them on...in a small provider community, particularly on working through MIPS and the new advanced payment models and we're trying to get to them also about how they can do the administrative transactions; it would be a great opportunity to really leverage that collaboration and not be coming at them from different perspectives.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Yup, agreed. Thanks.

Lorraine Doo, MSWA, MPH – Senior Policy Advisor – Centers for Medicare & Medicaid Services – Health & Human Services

Thank you.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Thank you and final question, Donna Cryer, on the phone

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Yes thank you. So I'll keep it quick because frankly the first...of the previous questions have been so wonderful. So, very high level, a concern of seeing quality on one side and patient safety on another side of the line on the slide; I think it was partially addressed under the protect patient's health provision but I just want to voice a concern since quality of course is a...safety of course is a prerequisite for quality.

The second point along the same lines but slightly different is I applaud the evolving language for advancing care information, because I feel that it does place the appropriate emphasis on clinician engagement and I think some of the tensions that have been around interoperability and engage...and patient engagement have been in the attempts to measure and hold accountable parties who are outside of the system, i.e. patients and families and holding clinicians responsible for our activities.

So...but I do want to make sure that we are keeping an appropriate weight, not merely an asterisk on advancing care information and understanding the difference between interoperability and data flows because they are a predicate and not a substitute for patient engagement. And so just with those two simple principles, I'll reserve the rest in any details to comment submissions and thank Kate and CMS for this really complex and robust body of work.

Kate Goodrich, MD, MHS – Director, Center for Clinical Standards & Quality – Centers for Medicare & Medicaid Services

Thank you.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So thank you everyone for your participation and really want to thank Kate, her team, CMS and ONC's participation. This is a wonderful piece of work in terms of listening and reacting and trying to construct policy that would help everyone participate. And it does mean it's complex and we look forward to all the comments. But thank you so much for the tremendous amount of work that's gone into this.

Kate Goodrich, MD, MHS – Director, Quality Measurement and Value-Based Incentives Group, CCSQ – Centers for Medicare & Medicaid Services

Thank you very much for having me; appreciate it.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Okay. And we did have permission from the next group to use this extra time, so thank you to the PMI group, and that is where we're going to move into. I don't think Lisa's available, correct?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yeah. So this is the Precision Medicine Task Force, is a task force of the HIT Standards Committee. There will be recommendations in the presentation that Leslie and Andy will be presenting to us, so please pay attention Standards Committee members because we'll be expected to comment and approve those recommendations at the conclusions of the comments.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

There will be a test.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

That's right, there will be a test. I think Jon set this task force up well in his introductory comments, you know I think everyone understands the importance of precision medicine to the healthcare delivery system of the future; so I want to thank Leslie and Andy for their presentation and the task force work in advance, and over to you.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So thank you and we intend to be precise. And as the other...as Kate said previously, it's almost impossible to see the screen from here, without binoculars; we're just looking at our own little copy and advancing it along. So we have a little agenda that you can see...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Andy move the mic up.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

I'm just mumbling, sorry. And that's the very invisible roster of participants and then beyond that, our goals. And we've been through all this material before so I'm going to whiz through it very, very quickly.

And then this was our charge, we...just take a little bit of time again to say that we were asked to identify opportunities for ONC to support Precision Medicine Initiatives and related health IT and interoperability challenges. We were asked to identify opportunities for ONC to collaborate with industry and pilot the use of standards in this arena. And then finally to identify standards for use cases to support the interoperability of data types that are critical to PMI-related research.

Okay, this is the second invisible list of all the things that we did. Again, we were very, very precise. So moving to the next slide. We tried to ask from all of the different stakeholder communities that came to the committee a series of common questions; so these were among them. What kinds of data sources were available? If there were gaps in high-value data related to or needed for PMI, what were they? What efforts could be made to accelerate or help the work of the precision medicine initiative? And were there areas in which standards could be recommended to promote scalable and repeatable development for precision medicine?

So, we realized after hearing a number of presentations that the volume complexity and new sources of data would require an emphasis on access and lots of query-based data exchanges versus just moving big data sets back and forth. Key queries and standards around these queries were going to be necessary, but volumes of data inherent in these queries and in these exchanges would be well beyond what is currently encountered in our newborn but growing EHR ecosystem. And that there were going to be lots of data sources that we weren't currently including, and especially data directly from the patient.

We've heard that over and over again that it was going to be extraordinarily valuable to have that kind of data. That genomic and other data from certain research platforms and labs and registries was also going to have to be included. And again, this stuff, some of it sits in EHRs, but some of it sits outside of EHRs today. And that it's important to recognize that this kind of data is not, well it's not static, it remains quite valuable over long periods of time as opposed to certain other kinds of lab tests for example; and so that the validity of the data and the quality of the data must be preserved over time.

And there are some interoperability pathways that are very important to the Precision Medicine Initiative. So we want to use existing standards where they are present, we want to accelerate and coordinate the development of some standard initiatives in support of this PMI and particularly in the realm of patient generated health data. There are some standards today, but there need to be more and advanced work on them. So this...all this design needs to be informed by the Interoperability Roadmap, guidance from the NIH and from others that are managing the PMI and so on. And I turn the graphic over to Leslie because she understands it better than I.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I doubt that. So we really tried to focus on areas of information coming from the EHR to the NIH PMI cohort coming from the patient. So the upper part of this graph represents that area as an immediate need and source of information. Concurrent with that, we also believe that we needed to accelerate the ability to return individual patients aggregated information from multiple sources, which is line three and eventually research results. There was strong desire of this idea of reciprocity; when I give information I expect something back, whether that's the patient or the organization enrolling the patient.

The second area represents data-gathering from multiple other independent, non-provided sources. And we think those will grow in the future, but lines one and three represent more of the immediate need. There was a lot of discussion about the complexity that this brings, but because there is, as Andy mentioned, this isn't document exchange per se, this is much larger than that. We needed to think more broadly about how information might be moved and including in that initial phase, in the first section taking information directly from the patient using something similar to the API approach, that we'll hear about later, from Josh.

So our recommendations really fall under three main categories; interoperability and data reciprocity, policy considerations and standards and APIs. So we would like ONC to consider to provide the Interoperability Roadmap addendum to PMI. And in this addendum would include an inventory of all of the data flows envisioned in PMI, the standards that are being used so that we can constantly understand and see, especially in the Standards Committee or other bodies overseen by ONC, what is actually happening and where the data is moving so that we don't end up reinventing multiple wheels.

We also wanted to engage stakeholders to accelerate the definition of minimum data set for patient generated data or phenotypic data to be sent to the NIH. There's a good deal of discussion about maybe there's a top 100 and understanding that this data set would grow, but there seems to be industry recognition of the need for this kind of information as demonstrated by the Genomic Alliance or Genetic Alliance I believe it's called.

And then we also want to provide ongoing guidance using technical expert panels considering this roadmaps efforts and informing the research committee on interoperability with EHRs and standards in general, so that we don't end up having just a disconnected ecosystem continually. The research will get information directly from the patient that may not be going through the EHR; how do we coordinate and align and harmonized some of these efforts? Are we on the next one?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Can't tell.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Or the next one.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Oh well.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Can we get the next slide? Thanks. So we also want to put emphasis on high value, non-EHR data sources to promote the completeness of the longitudinal patient information so things like using the standard-based API approach to get medication history, adherence data; potential sources coming not only from the P...the patient themselves, but also PBMs, retail pharmacies and others. Labs we should consider the challenges in pulling data from commercial and hospital labs and explore practical differences between lab data in the EHR versus data directly from the lab to determine which set might have greater fidelity and value.

Also there was a large discussion about how claims data can enhance the understanding the patient and the sources; so to encourage the use of claims data as well and that PMI should consider means of patient-mediated data donation to reduce probabilistic matching. And along that line there was a common concern about the more data you have, the more likely things can be matched to a patient. So how could we make sure and protect the data from that kind of a matching for potential use by miscreants.

And there was a presentation I think we had from, was it NIST that talked about having the identity repository somewhat separate from the data repository and that there had to be actions of matching that took place and were quite deliberate, rather than this a large bucket, as Andy said earlier, this bucket of data will sustain its value, it's not episodic in nature, it's for the lifetime and beyond the patient, so there's additional consideration that should be taken into place.

Also we felt that the participants' access to their aggregate information will promote participation and retention. So data return should offer dynamic...lost the slide, okay. I'll say next slide, sorry about that. I think we're on the same slide, yup...the data should offer some dynamic and compelling visualizations to promote its use and patients should have access to computable raw genetic testing and sequencing data. Over and over we heard that this data could be very useful to patients, whether it's today or in the future. And that the patients will need provider support on the implications of their genetic data, education would be very important.

And near-term we believe that access...we need to access and accelerate individuals' ability to retrieve their information, we recommended patient-facing portals that enable individuals to access all data types. Portals should allow individuals to use Apps and APIs based on existing and emerging standards like FHIR and draw from stakeholders with relevant strengths and experiences like things outside healthcare, Open Humans, PatientsLikeMe and Open Notes.

We're next slide on policy considerations, it's number 15 if those of you are following along. Michelle, do I need to pause for the technical difficulties or are we okay?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It's okay, it's just in the room; on-line they're still able to follow along so.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, so online, just go to slide 15. NIH should educate patients and providers of data access rights and uses. This was really very strongly felt that there's a whole area of privacy literacy that is beyond just what we're talking about in the electronic health record, but also in the use of data and consider the framework for responsible sharing of genomic and health data in developing exchanges.

Enrollment should include notification of use and the patient NIH ID. So whether that is to notify back to the provider or to the patients themselves, making sure that there is ability for that patient or provider to have record locator services or find that data in the future. And that direct enrollment should include strong assurance and identity proofing equivalent to the current patient portals model and what we see in the API recommendations coming later this afternoon. Use very specific language and employ Web Content Accessibility guidelines and accessibility for enrollment.

We also believe that gathering patient data from a variety of sources will have implications for identity matching and the task force recognizes that significant efforts are currently underway. Consent and authorization with common theme to inform patients of identifiers used and consult regarding its use; there was discussion about notifying patients for future harvesting of data as well under this discussion. Clarify if content is it applied to copies of data so patients understand that if they grant use today, that might be used again at a future date, consent should accommodate that.

And we recommend that OCR should confirm if consent is required for a provider to receive access to the NIH data when a covered entity enrolls a patient into the cohort, does this fall under the typical care, treatment, payment or operations. And the data access rights should apply to genomic and phenotypic information and use notification to patients and providers when the data was harvested. Next slide, 17.

The task force recognizes that there are efforts underway to address access and clarification to related policy that would facilitate patient data access and return of results, privacy and security implications of returning an individual's aggregated data, and that's the aggregated data, for instance the patient-generated data from multiple sources or other sources that are aggregate now could provide continuous benefit in care. And the options to types of data patients would like to access and receive.

There are some issues that we still need to think through on liability and consent; the granularity of permissions and back to the timeline and value of this information over a much longer period really implies a new level of consent and potential questions around liability.

We felt on slide 18 that the data formats participants should be constrained to using specific EHR export formats or API level formats and data recipients may need to anticipate a certain level of effort to translate data. We also felt that consensus-based models can facilitate exchange like the DAF framework and Argonaut be informed by things like PCORnet, Sentinel, NCI, and others, as well as work being done in the Veterans Administration mapping.

On the individual data, for data donation and return to patient use consistent with FHIR-based APIs like the Sync4Science Project, Argonaut and SMART, and that new FHIR resources may not be needed immediately, but an extension of existing resources may help. And FHIR will become more necessary as it continues to evolve. Next slide.

So as a health provider organization enrolls patients' behalf, it should include patient generated data when possible, but patients can act as their exchange mechanism among their providers and act as the data source for provi...data not captured in EHRs. We encourage that to be used by NIH so that not only the data's coming from the EHR, but the patients themselves as the patient intermediary...mediator. Promote standardization for use of PGHD and recognize that standards will be evolving. And this is really early days and that sentence, "standards will be evolving ongoing," we feel is one of the reasons there needs to be that interoperability addendum to the roadmap for PMI. And EHR sources for episodic and demographic information is great and the common clinical data set is the minimum bar.

Standards-based App and API implementations is recommended to enable patients to connect to EHRs with Apps and APIs and share that information, and enable patients to mediate exchange and also provide ability for reciprocal queries from the EHR for patient-specific aggregated requests of PGHD .

There are some things on the parking lot. We still are curious information demographic data, specific activities or pilots in ONC could lead to support advanced progress. Patients' rights and ownership of genomic data, although this group was continually very vocal about access rights should be the same as any other PHI or EHR data. And questions about record locator services on identity management, how will that be handled? And apparently that work is going to be executed by the Coordinating Center's awardee.

And the genomic data we really did not dwell on, that's being handled elsewhere. Our group focused on what's coming out of the EHR, what's coming from the patient and the minimum data necessary to do that. So with that, we'll open it up to questions and comments.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

And I just want one final comment; the patient's rights here are absolutely paramount. I don't know how many of you are familiar with the saga of the HeLa cell line. And if you're not, it's instructive, it's actually been written about for the lay press, but this was a patient's material...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Henrietta Lacks.

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

Henrietta Lacks and she actually didn't consent to having it used and her children and children's children sort of figured it all out and what the implications for them were. You know, it...this is just large. What if your gene is a really important gene, what's your right to control the end use of that gene if you've given it up in Sync4Science? Anyway, it's not clear, none of us here are going to have the answer, but that it is a question that has to be wrestled with is in no doubt.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Rights of use, rights of ownership and the fact that that...the data persist for such a long time, its value persists as long as it was something that we heard over and over and over again .

**Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP;
International Health Terminology Standards Development (SNOMED)**

So thanks again to all the members of the committee who are here today and to the ones who are not here today. They worked very hard and really were very diligent in their discussions. We think it's a good product for you all to consider.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great, so umm thank you to the task force chairs for the presentation. We're going to open it up for comments. I just want to remind particularly members of the Standards Committee that the material in slides 12 through slide 19 will be reformat as a transmittal letter with specific recommendations and with respect to the deliberations in Standards Committee and approval to report that out, that's really the material that's going to form the core of the recommendations.

On that note, just one question for the Co-Chairs, I understand slide 12 to be recommendations to ONC slide 13 and 14 to be recommendations to the PMI kind of cross governmental group. Slide 15 to be

recommendations to NIH, and then I lose the thread a little bit for slide 16 and 17 where you're making policy recommendations on privacy, consent, access, liability. And so I might suggest an amendment here that you're recommending that ONC coordinate with OCR and NIH relative to those elements.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So noted, thank you.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Okay, thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And then 18 and 19, I believe you're making recommendations for ONC to coordinate with NIH relative to data standards.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yup.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Perfect. Thank you. And so now we'll open it up and I will start with Rich.

Richard Elmore, MA – President, Strategic Initiative – Allscripts

So really a great piece of work. Thank you very much for all of that. One question I had...I'm fully supportive of the recommendations of the group. One question I had though was a lot of the direction of the information is from the clinical to research, did your group work at all on thinking about the feedback to the clinician and kind of how that...

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

We did, and I think that's in the graphic. It's important because we felt that that's been ignored. It was the third bottom swim lane; so it's feedback not only to the clinician, but also to the patient about individuals as well as populations .

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

And how does that go into the recommendations?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well we talk about getting some guidance on what the...specifically the provider organization that is actually enrolling on behalf of the patient; what rights do they have then for retrieving that information for ongoing care? Does it fall on treatment, payment or operations? We did not have a clear answer, would like one as part of the recommendation. At a minimum the group recommend that the patient ID be shared back and perhaps a record locator service so if there was a future need for care that could be done. But there is a gray area there and questions came up on, well do I get to access that once or is

that for the life of the care of the patient, the life of the patient or beyond? So there's a lot of question about access and use so at a minimum we talked about an ID and record locator service as a minimum.

The patient, however, there's strong information or strong request the patient have access to the data itself from NIH, not only the genomic data, the raw data, the results, but harvesting information one thing is harvested and used and also information is sent back to the provider. So there was a lot of concern and questions about this and emphasis that the consent should have include this kind of idea in the future. We didn't have all the answers but as we dug, we had a lot more questions. It's still early days, but in general there's that threat of, you need to protect us a little bit differently in that the data has a much longer lifespan and value and in fact might have increasing value over time and that requires some additional protection.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, so I think Rich, that there's a recognition that feedback to individual practitioners and to healthcare delivery systems needs to happen and that it's never been done this way before, so we didn't know exactly what to recommend other than it needs to happen and we have to have the right policy and standards wrapped around it, so that they can use the information for care delivery as needed.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great, and lots of cards going up. We'll go to Anne.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Thank you. You may have just answered my question. Great work by the way to you in the committee. I endorse your recommendation on the raw data be made available to the individual, but that can be extremely large sets of data. I'm just curious, which of your business scenarios on your slide you saw that happening through? Because I think it can be challenging to go direct back to the patient; so were you looking at that primarily going to some kind of repository like an EHR, which can also be challenging?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Well we talked about the NIH or its designee being the actual repository and access doesn't necessarily mean download...

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...it means access, right? These are volumes of data. We would anticipate that when there is a particular unique sequencing being ordered, for purposes of care, that would be shared back to the patient as any other type of ordered result might come into an EHR. So we felt that it wasn't necessary to state that over. However, the access right was talked about over and over again, but not necessarily for movement.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great. Kathy?

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Yes. Congratulations really on a very thorough report on a very challenging topic and obviously you're foraging new ground. So a couple of questions come to mind; and one does go back to the slide that's on the screen right now that shows the three swim lanes. And from what I'm seeing here, on that bottom swim lane it would always be the return of information to the provider as you envision it, would always be preceded by a decision on the part of the patient to share that information?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, and implicit in a sort of care arc is that the patient's already decided that and so if I have a test today, you know I'm expecting my practitioner to act on the results. So the nuance here is that there may be information broadly in my genome that isn't going to be involved directly in my care today, but might be involved in my care five years from today, or in my children's care and how do I make sure that I have some control over whether that information is accessible to practitioners.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And this gets back to that, when does the provider have the right to it directly in treatment, payment or operations? We don't have clarity on that so absent that, there is this assumed that the patient is involved ongoing or at any point, your children, I mean this is really new ground for us and understanding the nuances will, I think cause a lot of necessary diligence.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So again, I think where you might've been going with the question is, it doesn't always have to come through me before I decide yes, it's okay for you to use this in taking care of me today. Because you've already had that discussion and it is implicit in my consent to have a test done. But a certain amount of control in general probably has to be both policy, policy provisions for the control and a technical architecture for the control have to be there and it belongs to the patient.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

So where I am going and I think partly it is to forecast or anticipate some potential issues going forward, would be that I may have a rela...so I'm now putting myself in the position of the patient, which of course all of us will be at some point, but that I may have a relationship with a provider today, but five years from now I may not have that relationship at all. And, in fact may want that information withheld from that provider if we parted on, shall we say, less than favorable terms.

So I think that an area for future work will be the time sensitive nature of permission giving. I think that there is also, it's possible that individuals who have their genomes sequenced will remember for the rest of their lives that their genome has been sequenced. But perhaps they will not and where or how they

can access that data and show, let's say 20 years from now it would be I think beneficial to have ways to go back to that genome which presumably has not changed, except probably for some epigenetic changes and be able to have a locator system so that I, the clinician, so I'm now sitting in that chair, don't just order another genome sequencing...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right .

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

...when it's been done once already, so...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

That's why we felt it was important to have a record locator service and an ID from this as a bare minimum .

Andrew M. Wiesenthal, MD, SM- Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Well and I think what we heard is that they do intend to have a unique ID and already have developed the technical aspects of that.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

And so then a, now in the clinician's seat again, saying to somebody do you have that ID, do you give me permission to then go to the repository and see if your ID shows up and if I'm able to see the select sequences that I am looking for?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

Kathleen Blake, MD, MPH – Vice Present – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Okay. Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great. Paul?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

I'm going to be carrying on the same theme and perhaps looking at it from a different perspective. As you pointed out, genome...your genome is the ultimate in self-described data, not only is it permanent, but it's all about you. And in order for it to have value though in the PMI Initiative, then as you suggested, you have to combine essentially all other data. So this really becomes an all data about you

sort of prospect. So looking at this consent, and I'm going to put it in the juxtaposition with the API discussion we're going to have and I wonder, my real question is, have you thought about it in that context, too?

Because if you think about it, as you enter into a healthcare organization, you have this cons...initial consenting that's for treatment; so that's sort of the once and done. Then this new version of consent, which you sort of talk about, it's sort of it's a once and over. It's...in other words, it's all your control is...the...because your control, it's over; you've consented and now it's combined and then it has the ability to go places and then so the consideration, the risk here is in the API world it's sort of once and forever because it's sort of connected.

Now, you've touched on this and I'm wondering did you could talk about how we should think of this API, this almost permanent connection with your initial somewhat innocent, like I've gone somewhere and I've done some...whether I've gotten my genome sequenced or entered into care or signed up for Fitbit, there's a lot of data associated with all those things to be useful in the way that we want it for PMI, it's got to be combined and then how do we deal with the gnarly issue, especially when we have this permanent connection.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So I think where we probably weren't clear is on the consent framework, we believe that consent framework could be temporal, it could be very specific data only. We would expect it to be a complex consent framework. However, we wanted to use the existing identity portion of consent where I presented to my provider, I've given him my ID, I've given him my insurance card, they've given me an access to my portal, I log into my portal, that was sufficient for the patient enrollment. So the identity, level of assurance for identity that that represents in that transaction was enough and we'll word that. But we feel the consent complexity will probably be much greater, but we wanted to make sure we weren't initiating a whole new identity process and registration process for the patient. Does that make sense?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So maybe another way to ask the question is: is cons...is appropriate and robust consent management almost a precursor to what we're all about to do?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, I think that it is and there may be both good and we didn't really discuss this in the task force, but there may be both good and bad examples already financial services today. So there's mountains of information, financial and purchasing information freely available about all of us. We have very little to say about who's using it, how they're combining it, and what conclusions they may or may not be drawing from it. And somehow that's okay, because it's happened invisibly and it doesn't seem to affect us in our daily lives one way or another.

But yet it maybe, it isn't, and maybe when you combine all of that with our genomic information and our phenotypic information and what we had for breakfast, it starts to get a little more intrusive and as a general policy issue confronting the country, I think it's quite serious and we don't know exactly how to handle it. There...we've talked about technical approaches to managing identity and consenting. But

how to really address all of the policy issues was way beyond the scope of our work and yet they are actually the more important of the three sets of issues.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We did get some testimony about the Framework for Responsible Sharing of Genomic and Health Related Information that I believe is coming out of the Genetic Alliance. But, so we didn't want to reinvent that wheel but part of our considerations was let's gather up what's being done so that we can be very specific about this work. But it was an undertone as a precursor for getting this; it's a Pandora's box that we need to make sure the lock's pretty good up front.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So is there recommendation not necessarily from this group but about the prerequisite policies that need to be in place for us to responsibly use this? Don't want to delay, but I wonder if there's...we need to have done.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

There are two basic...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And difficulty is that the PMI also assumes consent; if you're going to participate, you have granted consent and there is a workgroup ongoing and Jon can probably speak to this. But we wanted to make sure that a consent was not a one and done, that as you start to include the EHR data, you start to include these things, it has to be much more complex.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So I'd like to just clarify that this was a workgroup of the Standards Committee.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

There are two pages of recommendation that are more on the policy side relative to these issues, but I wonder Paul, if it might be worthwhile to relook at the policy issues here with a greater focus. And I'm going to then, and this is a super complicated area because you've got a thicket of research common rule, HIPPA, and FTC protections that may or may not apply in different circumstances. Vindell, maybe I'll push it over to you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We had both Policy and Standards Committee members in the...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yeah.

Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right.

Vindell Washington, MD –Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

I was just going to add to that. I think that's a very salient point that was made just about the fact that there are several policy pieces that have been important in our own PMI discussions leading up to this and working with the White House and others. And it would be very helpful, I think, for that to be added.

I had one standards piece to put on the table if I may, that is really around, we've talked a lot about the indivi...that information coming back to the individual for individual treatment. I think another point is around the findings and aggregate and I was wondering if you might have a consideration to standards around clinical decision support as you sort of provide input back to practitioners about the findings and aggregate, so they might help the next patient that's coming in.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

We did not talk about that but I think it's a great parking lot item.

Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, I'm going to switch over to the Chair Emeritus, Jon, if you want to provide comments .

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

I'm getting older every day. So first comment, boy am I glad you guys are on this journey with me; thank you. The fact that everybody going around was like, holy smokes, good recommendations, should tell you something. Just a couple points to embellish or elaborate on things you said.

My colleagues at NIH would want me to say, you asked something about NIH holding...or you in passing mentioned something about NIH holding the data. NIH would not hold the data...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

...the Coordinating Center will hold any aggregated data that...which and the Coordinating Center will be a grantee cooperative agreement. So, that's just as important for you all to know, NIH does not have a box of data on the NIH campus.

The second thing, great points about educating patients, participants and providers on data access rights; you know, you brought up the issue of, what access do we have under treatment, payment and operations? I will proudly point to my colleagues Christina Heide and Deven McGraw working at the

Office of Civil Rights, an integral part of the Precision Medicine Initiative and will be working closely on an ongoing basis with all of us to try to flush those things out, certainly of course working with from the smorgasbord of NIH funding opportunities direct participants engagement, healthcare provider organizations, funding opportunities. So, I think that...I think those are great thoughts, we'll make sure that those kind of make their way to the right places.

Your point about the compelling visualization and other ways of engaging people in getting their data back to them; yeah I just wanted to call back, you know we focus so much on some of the awards; I want to make sure there's a...that we don't forget that there is a pending award on a participant technologies grantee that will complement the Coordinating Center and healthcare providers and the direct volunteer enrollment and the biobank and is specifically meant to kind of address a lot of the great points that you all raised. So, all wonderful thoughts; I just wanted to add a little bit extra to the conversation. Thank you.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks Jon. So noted.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great. So very patient, Carolyn?

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Thank you. I want to complement the committee on this very comprehensive and thorough work. I know there are lots and lots of very complicated issues to be covered and it strikes me as a really fine piece of work. I did want to see clarification of one of the points in one of the slides, specifically, slide 16. There is a sub point, employ a consent framework that enables new and/or expansive consent as new data needs emerge. I'm wondering if you can clarify what you had in mind with that bullet point.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So, they're sitting on the data and it's been accumulated for a specific purpose or was donated as a part of a patient's altruistic motivation at one particular point in time. And somebody wants to do something new that wasn't previously contemplated. There needs to be a framework that allows the participant to essentially re-consent. I didn't...I gave it for this purpose, these are the things that I understood you were going to do with it. Now you want to do something completely novel; I need to be informed and say yes again.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

And also the new data coming in might enhance the value of the data the person donated.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So there's not only new use cases that Andy mentioned, but there might be new understanding, new value; so just making sure that this is always an informed consent process.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

So we would like to give you more information about yourself, here's what you could learn and so it's about that return arc that we have talked about at several junctures here.

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Thank you. I appreciate your confirming that you intend to involve a re-consent process in the recommendation.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And Michelle, I think there's somebody on the phone?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Gayle Harrell?

Gayle Harrell, MA – Florida State Representative – Florida State Legislature

Thank you very much and I'll be brief, but I can tell you, first of all I think the work is the very beginning of something that will have long-term benefits. However, we to a degree are opening a Pandora's box and I think the consent issue present major problems. We're entering a brave new world of patient data here and when you talk about long-term implications of storing data, where is it going to be stored? Who is going to have access to it in 10, 15, 20 years?

And this is data all about you, this is a total composite including genomic data. I can see many discussions in public arena about this. I think as the task force moves forward the privacy and security subgroup needs to really have a very public conversation about this. Otherwise, it's going to be a lot of pushback about it.

I think also when you go and you start talking about a unique patient identifier and certainly I can understand the need for that, but we do have legislation out there that prevents that and I don't know how you're going to address that. But there are many, many conversations that need to take place on the policy level. Certainly, the standards level is significant as well, but this is going to be a long-term conversation and I think we need the public very much aware of and involved in; otherwise, there's going to be a huge pushback.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Just two comments; first of all the committee although it wasn't broadly advertised and wasn't, you know number one on the hit parade, it was actually a public committee and the public could listen. And I think you're absolutely right that that needs to happen more and more. Secondly, I don't think there's anything inherent in having an identifier for this purpose that's prevented by law.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No, it's a record identifier or, so I now have an identity associated with me there. It's not a national identity, it's just yet another identity that we need to keep track of.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Right, you have to keep track of.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I just, I also want to remind the committees that the PMI is a broader initiative of HHS. So this task force doesn't have oversight over PMI, but is making recommendations back to ONC and to PMI relative particularly to standards and interoperability considerations. So, I presume that NIH has the appropriate process to review public comment and considerations relative to the issues that Gayle just brought up. Vindell, you had more to say here.

Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So I'm sorry, just one last comment. I did want to thank you for the clarity with which you underscored the need for patients to receive the testing data and the detail with which you went through that. I do want to underscore for the group, and I know you're well aware, because it's listed in your parentheticals that today there is work that would have to be done and a lot of research instances to make that possible, research labs aren't generally covered under CLIA. So the idea of being able to return patient specific data and some of those instances would be work that would have to be augmented as you look into the future. So not so much as a comment on a change in direction, just sort of underscoring what I think you have laid out here and the change that represents for the research industry.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Mm-hmm. Thank you.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Getting data back to clinical trial participants often has not been a number one priority. So I think we're done with the comments from the committees. We will now go to see if there are any objections, particularly from the Standards Committee, although I think we'd love to hear particularly objections to proceeding from the Policy Committee as well. Going once, going twice; okay so in the absence of any objections, we will proceed forward with formal recommendations to ONC and to other stakeholders. Thanks to the task force Chairs for their fabulous presentation and the members for the...all the content.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thank you. I'd also like to recognize Mazen Yacoub, who's ONC staff who did a fabulous job for us.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

Yeah, they were absolutely...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great, thank you. So Michelle, I think what we're going to do is reorder the agenda and rush Steve onto the stage.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

All right. Are they ready with my slides? All right, sorry for the delay. Yeah, I should've brought my own version, too. I left the printout of the printer before I came here, so, typical story. Before I dive in there are certainly people on my team that I need to recognize, Tracy Okubo, Caroline Coy, Mera Choi who have all led the efforts that I'm going to talk about real quick. So, wanted to acknowledge their efforts given that there's a lot of work that always goes on behind the scenes and I am here today presenting them.

So as a reminder to my Health IT Standards Committee colleagues, you issued recommendations about a year ago, rounding down, you know relative to a number of standards and interoperability issues that we solicited your recommendations on, and I chose a few excerpts from that recommendation letter that I wanted to update you all on in the context of the work here.

So the first one being that we should support a convening function that focuses on full, you know on the following key enabling activities, which is kind of the broad overarching recommendation that the Standards Committee provided. And the action that we took here was to evolve ONCs organizational approach to standard and technology efforts to align with, as I described to you previously, Tech Lab and the four focus areas that we've got in it, standards coordination, pilots, innovation and testing, and utilities.

So that is how we at a high level re-approached and evolved how we were going to engage with industry, how we were going to organize our work internally and that's really been the primaries about which we've been working on throughout this fall...the fall into the spring when we formally publically announced that transition.

The next was to work with SDOs and coordinate with SDOs and perform additional activities to support identified national priorities. That we've...have since executed two cooperative agreements with HL7, a bolus of which is focusing on Consolidated CDA right now as an identified priority. The second one is with NCPDP and we also participate in what used to be called the Standards Charter Organization among the many SDOs together. I forgot the name that we recently came up with when everyone was there in terms of rebranding that a little bit in its new environment; but nonetheless we do engage with that group of multi-SDOs as well.

And then specific to the presentation today, there was a recommendation around supporting the production use of these above kind of components by facilitating, including federal funding pilots in effective production, implementations and adoption. And I won't read through the elements here, but the action that we've taken thus far is to launch the interoperability proving ground, which I think many of you heard me ramble on about before.

That's an open community platform where you can share and inspire others by kind of posting what you're working on and tag that information. And there's some recent subscription features that we included as well. You don't need to post a project to be able to follow particular projects or tags that you want to follow to be updated on progress or happenings that are going on.

There's also an interactive map so you can see what projects are going on in your state. And you can subscribe to your state as well. So if you want to know what's going on in New York, you can just simply subscribe to New York and then anytime a project gets added in New York State, you'll get notified at your specific frequency that you select.

And then the next is, what I'm here to talk to you about today, we recently announced I think at Datapalooza, that was last week already...today is Tuesday, these two new cooperative agreement programs, one which we call the High Impact Pilot, and that we call Standard Exploration Cooperative Agreements, so, you can go to the next slide. That might be me.

All right, so here's kind of a game board, that's if you can't do it in a table, then it's hard to explain. So for both of these funding opportunity announcements, the approach and the focus was the same; the specific requirements and scope are what are different. And so the approach that we took was to frame three priority named categories; one around medications, one around labs, and then one around care coordination.

Within those, we prioritized a few subcategories of particular avenues where we said, here's really where we're interested in funding particular pilots and then the last one, in a kind of being humble technique, we were also open to a bright idea that anyone could propose that we would toss into the mix as well; so that's really that self-identified category. It's not the...if you submit a proposal for this category, you won't get funded type of thing, it was more us being, you know again humble and saying if there's a really bright idea, especially if they touch on the standards exploration award that we hadn't considered in our specific areas that we're identifying from a policy and program perspective, we wanted to signal our openness to kind of out of the box ideas and suggestions.

So people start at the left side there and look at the categories and the areas that we've prioritized. And then for the High Impact Pilot award, they have to address three of the seven identified impact dimensions. So what we really want out of these pilots is, specific areas of focus, specific areas where stakeholders that'll apply to be awardees will say, we are going to try and tackle these three things as part of our pilot approach.

The difference between HIP and SEA, as we refer to them, is that with the Standards Exploration Awards, you only have to do one impact dimension. So they're smaller in funding and financing compared to the High Impact Pilot and they are also smaller in terms of scope. So if you're going to do a Standards Exploration Award, you may pick, as I tried to frame the examples there, you may say, we want to do a pilot around medications, we want to do drug cost of care thing and we're going to look at cost efficiency aspects in terms of how we want to find that. And so that would be the focus of that project across that impact dimension.

With respect to the overall availability of funding; for the High Impact Pilot Award the total cumulative funding that's available is \$1.25 million. We expect that to kind of shake out into three to seven pilot

awards, if I got my number accurate. And the range of the award that we expect for the High Impact Pilot Awards is between \$100K to \$500K. Obviously that'll affect the number of pilot projects that we can fund out of that bucket of money. And then with the Standards Exploration Awards it's a cumulative bucket of \$250,000, in which the projects that we expect to fund will be in the \$50-\$100K range.

So these again, from a smaller sized scope, but it could be, you know someone looking to pursue an emerging type of approach for standards and technology implementation, they could first apply for Standards Exploration Award funding this year, prove it out, learn something, fail fast and then come back next year with a better idea that may be ready to scale at a broader level to the High Impact Pilot award type of approach.

And the other two aspects that I would emphasize, which may be informative to Rich's task force as well, you know many questions have come up in terms of how we're going to be using the Interoperability Standards Advisory; this is one example where we've translated that into practice saying, look first as you apply to everything that's listed in the Interoperability Standards Advisory. You are expected to pick things and choose off of the Interoperability Standards Advisory to help the industry make progress to pursue, to look at the adoption level at particular interoperability needs. And if they, you know, this needs a little bit more evidence, we need to get some proof, that is the kind of guiding document in terms of what we expect people to start with.

We recognize that it's not comprehensive or exhaustive at the moment. So again, it's a kind of humbling acknowledgment that you're not prohibited from picking something off of the Interoperability Standards Advisory pick list, but it really should be place where you start with in identified areas already that we have signaled particular standards that are there.

And then the last one is perhaps as agile as one can be in government, you really need to be ready to hit the ground running. We expect these pilots to be performed within a year of performance. So for those that are considering applying, you really need to have your act together, your thoughts you know consolidated, and really make your best proposal and best foot forward toward the funding announcements.

With that, those are my two slides. But I wanted to again frame and do a little feedback loop for you all that we do pay attention to your recommendations, as always. And we are acting, you actively to implement them. There are many others from that letter that I would also at another time, you know I could certainly touch base and describe what we've been doing relative to those. But those are the top three specific to the recommendation that we provide and step in to help with some funding for pilots.

And as we pursue the work that we're going toward in the future, we can certainly look at other opportunities, provided that these are successful to build on them or to look to transition to a different avenue. Thank you for your time.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yes, Steve at one point reminded me that the time delay from the recommendations to ONC action actually represented a rather speedy effort on behalf of ONC to re-jigger procurement and contracting and a whole bunch of other things that need to happen on the backend to make stuff happen on the front end. So hopefully we all have the appreciation of how much work it takes to move the machinery.

So I think we've got a couple of comments here from Kim and from Leslie. So let me start with Kim because we've been starting on the left and now we'll start on the right,

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Thanks Steve. I quickly looked online to see these awards; it doesn't seem like there's a lot of specifics about the parameters like the comprehensive medication management and the drug costs that care and the opioids. It's the drug cost that care the patient cost or are you looking deeper at a total cost that would include full transparency?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

Can you be a little bit more specific about your last distinction?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Well, there's a cost that's there but then there's typically rebates with those medications. So is it the cost of the patient at the time of care or...because when you look at total cost, there's other costs that are in there that aren't always visible, so I'm...

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

Sure.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Let me give you an example here; I've got...my son is on a specialty med that costs about \$10,000 a month. My out-of-pocket is zero. That out of pocket gets to zero on the basis of my hitting my out of pocket max actually from a health plan, but also on the basis of rebates that are applied on the back end from the manufacturer. Although the cost to the payer actually is the full and total cost of care; so the difference between the total drug cost that the payer and the patient together are paying relative to the patient direct cost of care; I think that's the point you're trying to make Kim, right?

Kim Nolen, PharmD – Clinical Informatics Medical Outcomes Specialist – Pfizer, Inc.

Right.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

Yeah, no that's helpful, thanks. And the one other caveat I need to mention is that these are funding opportunity announcements, so without lighting my grants colleagues' hair on fire, I have to be careful about how much detail I get into. There are going to be, good segue into we will have two information sessions for each of these funding opportunity announcements that will be coming up in the next week or so, so I would encourage anyone listening to tune into those. You can access them on our blog post.

But to your point, you know I will start from our initial thinking around, we know that there's been work you know with NCPDP and others in the pharmacy community to give prescribers and patients a better sense of how much drugs would cost before they're prescribed. And that was at a high level, some of the intent so that there's greater transparency up front before you get to the pharmacy and they're like, yeah it's \$800 for this prescription and even with your co...you know, all your insurance coverage and

everything. So that that would be pushing things...the information upstream so to speak, to help earlier on as part of the prescription choice or what gets prescribed.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great. Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

You somewhat answered the question on the costs of drug care available both to the patient and to the provider real-time. But the subcategory of opiate I know there's a considerable need to know that information, but I assume this infrastructure is one that could apply to any drug so that patients can participate in shared decision-making about medication use and ordering.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

Yeah I mean, you know so we have not prescribed at a detailed level...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

...all of the particulars that we expect someone to submit in to us. I think that's some of the...going to be some of the differentiating factors as it goes through the objective review process where the reviewers would say, you know this proposal is really put together and the way in which they, you know see to approach it and prove to scale or prove its extensibility are...would be some of the things that would, you know...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Because I remember when we first started talking about this in standards, it was an idea we were going to download all this stuff and that became impossible and pretty much irrelevant after the first day you download it; so we wanted real-time access at a broader scale. So that would be highly encouraging to know that this was scalable.

And then my other question was, sort of a precursor to a lot of this was the need to understand provenance and duplicate management and that that was one concern we had at the time we talked about care coordination and care planning with adding new people, adding new...and new information, what we were going to do about that. Is that part of this project as well?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

I think that that could be certainly something that would be addressed by someone that would choose the privacy and security impact dimension and they would say like, we really want to get a better understanding of as these get deployed in practice, how we're going to deal with provenance, how we're going to deal with the duplicate records, the matching, etcetera. Those would be elements that they could explain that they'd want to take on in that category.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Thanks.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Michelle, I think back to you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Thanks Steve.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

It's always good to go before lunch, right?

Public Comment:

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

At this time we'll open up for public comment. If there's anyone in the room who would like to make a public comment, please come up to the table. As a reminder you have three minutes for public comment. And I'll turn it over to Alan to open up the lines.

Alan Merritt – Interactive Specialist – Altarum Institute

Thank you. If you'd like to make a comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So we have no one in the room and no one on the phone as well. So, perfect timing.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So we'll convene back at 1 o'clock.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yes. Thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Thanks everybody.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

If everyone could take their seats, we are going to get started. I know that folks are still finishing up lunch, which is why there are so few people in the room, but hopefully they will start to trickle in soon. But in the meantime, we are going to get started. The lines are open. So I don't know if Arien, Paul, Kathy, if you want to make in the comments to help kick us off; but if not, we'll turn it over to Josh and Meg.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Let's just go with Josh and Meg.

Michelle Consolazio, MPA Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks Arien.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I do want to remind everybody that this is a joint committee, so we will ask the full committee to approve the recommendations. And I do want to set this up by saying that in addition to the eight pages of recommendations that I counted, there's also no fewer than six pages of glossary items documenting every single word that may be problematic in the report. So this is a very thorough report out by the API Joint Task Force. So be prepared at the end of their summary and presentation to vote and...out on the recommendations that are in the extensive report.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Okay. Let me verify that I can move the slides around. Yes, this is amazing. So we're really excited to be presenting to you a set of final recommendations that we've put together. This is based on the draft recommendations which we present to you last month from the API Privacy and Security Task Force.

And first of all, let me just say we really appreciate the questions and the feedback from the session that we had back in April. And we've reworked and updated our document to include a few key additional pieces in response to that discussion session we had and in response to some follow-up e-mails. In particular to clarify further, what are the areas where we think business associate agreements are and are not appropriate when it comes to patient-selected Apps.

To clarify a bit about the scope of our project, which we'll talk about a little bit in the intro, but especially when we say that it was read-only APIs that are the subject of our focus. We've updated the document to clarify that a bit. And also when it comes to the concept of health privacy literacy, we've updated our recommendations to describe in better terms what we mean there.

So I won't go through the details of our API Task Force charge and the questions that we were set forward with, because we've gone through it already once or twice in this forum. But just very broadly we were asked to look at privacy and security concerns when it comes to health data APIs and generally in the scope of Meaningful Use Stage 3. And we were asked to leave out of scope, a whole long list of issues, which we did attempt to leave out of scope, although in practice our recommendations wound up touching on some of these issues in places where it really couldn't be avoided.

But the things that we tried to leave out of scope included, terms of use, licensing, policy formulation, fee structures, certifying authorities, standard formulations, electronic documentation of consent, and issues having to do with write APIs that can change the data back in an electronic health record system. So what we've done for this presentation is we have provided everyone with a copy of our report, which has about 30 pages of background, of recommendations and of outstanding questions that we wanted to leave on the table. And then we provided in slides, simply an outline of that document. And our hope is to be able to engage with specific questions that anyone on the Joint Committee might have about the content of our recommendations.

But just to take you very briefly through the document that we have shared with you, the document begins with an overview that talks about the scope of our task force, some of the motivation for why we chose to further limit our scope to focus on Meaningful Use Stage 3 patient-focused API access. We'll talk about some of the overall approach to the task force including our sense of general support for APIs and some broad questions about oversight and enforcement for access to these APIs. And then the document proceeds with a use case that identified eight key topics that we address individually.

And these eight topics include the different types of Apps and organizations who provide them, the process by which Apps register for access, the process by which Apps might be endorsed by outside organizations, the process by which we communicate an Apps privacy policy to patients, patient authorization of Apps to access their data. We include limitations and safeguards on the data that are shared. We include a discussion of auditing and accounting for disclosures. And finally of identity proofing and user authentication in topic number eight.

The document also comes with an appendix which includes, as Arien alluded to, a glossary of terms as well as some background on the process by which these recommendations were formulated in our group. So that's a very brief introduction to the document, the full content of which is included in everyone's printout packets. And you should have access to a Microsoft Word document that was e-mailed out yes...that was e-mailed out last week as part of the materials for this meeting. And with that, let me turn it over to Meg to see if Meg, you have anything to add before we delve into questions.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

No additions, just looking forward to the questions.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Okay. So with that everyone...we recognize that there's a long report that we've produced. We hope you've had a chance to review some of the content and we'd be happy to address any outstanding issues or questions.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Excellent. Let's see who in the committee has...I can see you guys have done the great move of extensively documenting, previewing and sending all the information out in advance, which is a great embarrassment for people who haven't read all the material. So we'll go first to Paul, Paul Tang and then to Paul Egerman and then, in the meantime, if anybody else wants to ask questions or make comments of the report, will please put up your card.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Great, thanks, Arien. So this is a question that's a bit of a holdover from the last time you presented your initial recommendations and then from this morning, when we talked about PMI and its surrounds privacy and protection of an individual's health data. So I'm trying to figure out based on the recommendations, I know you acknowledged people's concern about...because you made the statement last time about, no one should...anybody who can technically interface to your API should be allowed to do so.

And that made me nervous last time and I'm trying to see how you addressed that, because in your recommendation on page 18, it's talking about not have...ONC should not use endorsements, not

produce criteria for endorsements and you recommended the private sector does that. Then in actually recommendation 3 B, you say but the DoD, for example, might create a list of criteria by which Apps would be essentially judged.

I guess I'm nervous for individuals who donate data, genomic or otherwise, to a third-party and letting the third-party connect in a permanent way through these APIs without any kind of certification, endorsement, commitment, public display of what they comply with in order to give the consumer some kind of a chance of understanding what protections exist. And I understand...and we all understand the whole, I agree thing, you know so people click the I agree and all of a sudden you've agreed to a lot of things, a lot of which you don't understand, at least as a consumer.

So just like we were looking at the MACRA and the complexities there, the kinds of things discussed that were discussed this morning with PMI, there's a lot of complexity about the implications of having all that data aggregated together and how do we give the consumer a chance of having informed consent, I guess is sort of one of the bottom line, and especially if there's no...you're recommending there not be any federal way of qualifying, certifying or endorsing any of these Apps.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Great, so thank you for your questions and commentary. I think maybe I'll start with a few observations and we'll see what else we can address. So just a few observations about scope, given some of the issues that you raised, Paul; so the first one is, you know you mentioned examples of genomic data and other data and I just want to emphasize, that our scope for these APIs, the focus for our task force was what's called the Meaningful Use Common Clinical Data Set, which doesn't include in general genomic data. It's really focused on the common core of structured data that EHRs need to be capable of sharing in the Meaningful Use Stage 3 III timeframe; so just to set some of those expectations about scope.

You also raised a notion of sharing data permanently and I want to tease out the notion of permanency a little bit. So on the one hand when you share data with someone, you've sent the bits over the wire and now they have the bits; and you can't take them back in the sense that you can't cause them to unknow what they now know.

But we do certainly address the notion of, if you want to share access to your record on an ongoing basis so that a third-party application can continue seeing what's new and what new data land, in general we think that that permission comes with time windows on it. So a patient might decide to approve one time access or decide to approve access for a period of a year and we think that the systems, the API providers, have the ability to set some parameters there about how long those data can be shared for.

On the subject of endorsements, I think that you understood the meat of what we were proposing, which is we do want to see an ecosystem where providers, where clinical societies, where privacy focused organizations, where consumer rights organizations, where all these different players can speak out and say here's the Apps we like, here's the Apps that we don't like. And you're right that we thought it would be undesirable to try to have a federal certification program by which every patient facing App would need to be officially approved.

And for us, one of the key points here came down to, especially in a case where a patient might be writing their own App or an App for a family member, it's a system that won't scale quite that broadly. When it comes to helping patients really give informed consent and making sure that we...that they

know what it is that's being asked, the places that I'll direct you to in our updated report are page 22, where we added recommendation 4A around this idea of privacy literacy, and in particular suggesting ONC should coordinate to help pursue this concept, which we think this is important.

And also to page...the bottom of that same page, 4B, where we talk about the notion of support for a model privacy notice; and at the end of the day, to our overview description when we talk about the roles of various organizations including the Federal Trade Commission in terms of putting requirements on applications...to clearly communicate these policies back to consumers.

So those are a few of the additions and clarifications that we added to the document in response to some of those issues from last month. Meg, what am I missing?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So I think the only thing that I would add is the concept of informed consent is fairly complex and we address it in several differ...through several different topics. So we talked a little bit about the endorsement process and I think essentially what that is is a quick stamp; it's something that's very quick and very fast and could vouch for the trustworthiness of a particular App. But we also talked about the importance of the App disclosing and being transparent about its practices and policies through the model privacy notice. So we teased that out a little bit more in a different section.

And then of course we talked about the authorization process and what's important for the consumer to know. Navigating the environment, we tried to cover in the oversight section, how challenging this process could be; we've got several different oversight mechanisms, several different statutes that are informing this and different agencies that are contributing. Our recommendations really focus on the role of ONC that...to convene the agencies to try and make this more user-friendly, more consumer friendly, focus on education and transparency of those key components that are required for this, "informed consent." And then again, education around who's the appropriate oversight mechanism and what authorities they would have for enforcement if it goes off the rails and if the policies aren't followed.

So I guess that my only addition to what Josh mentioned, is that we tried to use the term "informed consent," we did include the changes around what I thought was a great recommendation last month Paul around the health literacy and how do we achieve that? Including languages and usability and things like that to the consumer. But ultimately what I think you're really doing is you're pointing toward what we recognized right off the bat was just a very complicated environment that really could use some harmonization around what the requirements are, and how best to comply with requirements.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So if I could just respond a little bit to your response? So, I mean it's always a fine line to walk in terms of what should you enforce to regulation essentially at the federal government level, and what should the private sector should do. And your heavy reliance on the private sector, which is all voluntary and could of course be very fragmented, just makes me nervous. So you look at air bags, there's lots of things that we do in the public's interest because it is too complex to assess what's effective, etcetera. This strikes me as one of those; that's just a personal opinion.

The other thing about the FTC, so the FTC can only enforce what you say, you know if you say something and you don't come through, then the FTC can step in. The bad actors obviously won't say anything like

that so that's why I thought your recommendation about DoD producing criteria against which Apps would have to disclose, would get some backing to the enforcement authority of the FTC.

So it seems like that's a hedge way; at least if you...if the federal government put out criteria, and it was up to each App developer to say, this is how I'm meeting it and then be challenged, you know open to challenge, the reliance on the totally private voluntary ecosystem developing just makes me nervous at least, as far as individuals being able to comprehend the implication.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So Paul, I think that's a really great point and it may be just semantics, the endorsement versus the model privacy notice. Did you feel that the elements that we recommended for the model privacy notice and how ONC could create best practices and ensure oversight of those that are sitting out, those statements in the model privacy notice, do you feel like that may be helpful or...?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

But, so did you recommend that they do develop the criteria or did you just recommend that something appear?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

On the model privacy notice?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

On the model privacy...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Yes.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So this is page 22 on to 23 in recommendation 4B; where we...what we recommend, but...so it's worth splitting these two issues out. Where we rely on the private sector is to say an endorsement, this App is good are that App is bad.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Doesn't that...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Where we do fall back on the public sector is where we recommend that ONC provide the criteria for a model privacy notice. And, you know that's an example where we're asking the federal government to take steps to make it clear to App developers what they need to communicating back to patients at the time of approval.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I'm going to take a Chair's privilege here and just try to tease apart some of these, just on a factual basis. It seems to me you guys were trying to harmonize two very appropriate policy stances; one policy stance saying that patients should be free to use the App of their choice in the way of their choosing, following HIPPA's stance that a patient should be able to access their record.

On the other hand, we have a desire by federal partners, by provider organizations to protect patients and make sure that data are used appropriately. And where you came out on that is, number one, recognizing a federal role for a model privacy notice and clarifying the policy rules in application. Number two, you recognized the provider organizations' desire to present endorsements and present fair warning to patients who use an App that does not come with endorsements, making it clear and potentially even including a click through warning making it clear to patients that, you know there will be dragons and the patients on their own.

And then number three, recognizing that the federal government in their role as providers and data holders who want to make an App...Apps available to patients have a role in ensuring common certification and endorsement requirements for Apps that they so endorse and that there's a public sector role in starting to jumpstart the private...the public/private certification mode. So that to me is the gist of the balancing act that you guys have described in these recommendations. I want to make sure I got that right.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yeah, I think that was an articulate and comprehensive summary of exactly what we're trying to balance.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great; there's been a number of additional cards that have come up, but we're going to go to Paul Egerman first.

Paul Egerman – Businessman/Software Entrepreneur

Thank you very much and I just want to say thank you Josh and Meg for a well thought out presentation of your material. And I also really appreciate the fact that you didn't force us to watch 15 or 20 PowerPoint slides, especially right after lunch and just went right into the material to give us more time for discussion. So I thank you for that.

And I want to pick up on what Meg was talking about in terms of education and transparency. And say that what you've written here is reasonable and noble. It would be very nice if the government were able to raise the privacy literacy level of the entire country. I'm somewhat skeptical that that will occur. I so believe and continue to believe that the transparency issues, the issues relating to the privacy notice really are matters that help the vendor and do not help the consumer.

That fundamentally transparency and privacy notices are simply a way to say to consumer or to a patient, if something goes wrong, it's really kind of your fault because you didn't read the fine print in the privacy notice which would have told you that this could have happened. And particularly the privacy notice will say that the data could be resold, the data is stored and resold, which might be something that patients do not fully understand because it is different. And these standard techniques of education and transparency, while they work, may work reasonably well in other settings like in like banking and you know, retail, I really question them in healthcare.

And the reason I question them in healthcare is the problems with unexpected disclosures are so much more serious. I mean, you look at something serious like what happened with Target and credit cards, not a single consumer lost a single dollar when that occurred. But you know, if patients lose a sense of

privacy to their medical records, I mean I don't know how you respond to that loss? How can anybody repair the damage that occurs?

And I look at this and I have to say I understand the image of what you're trying to create, you have this image that if we allow all these Apps to interact with HER, there'll be thousands of Apps, there'll be a lot of patient choice and that will benefit patients. I mean that's I think the basic assumption here. But I just see that there is very serious risk to this approach and in particular, you know you say, you know ONC should...provider organizations need to accept all of these Apps, regardless of the status of any lack of endorsement from any rating agency.

And, you know the rating agencies can rate it poorly on privacy, they can say the data is going to be resold. You could have a rating agency that says an App is detrimental to the patient, maybe it does dosage calculations incorrectly. And I think the provider organization needs to have the ability, probably has the obligation to block those Apps.

So I have to say I just disagree with that fundamental tenet. My view is provider organization should be able to block any App that they reasonably think is not beneficial to the patient or is detrimental to the patient. So that's my view and my comment is, because of that view, I unfortunately I will be voting no on these recommendations. I think this goes too far.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So first off, thanks for the comments and we agree that an ecosystem like this will pose risks and we also think it will offer benefits and opportunities. And so we want to be very explicit about recognizing that balance and that's the first thing that we try to do in our general introduction.

I also do want to call attention to a couple of places in our recommendations where maybe we said something a bit stronger than you might notice. So in particular, we talk about this issue of whether a provider can turn off access to an App, for example in a circumstance where it believes that this App is responsible for doing something untoward with a patient's data.

And so for example in recommendation 6C and recommendation 5B, we do describe the notion that a provider can turn off access in a way that might proactively prevent data from being lost. We also stipulate that at the end of the day, it's a patient's right to turn it back on if they want to take a positive step to assert that no, this was my intention. We just don't see any finer line to draw that doesn't leave the provider with the opportunity of "data blocking," and that's again the sort of balance that we tried to strike here.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

The comments that I would add, we did hear from providers who were very nervous about what this...if they were to be held I don't want to use the term liable, but for lack of a better one, if the expectations were that providers were to vet and understand the capabilities, possibilities of each of the Apps, that that would be something that could be very overwhelming for them to try to manage and enforce. So...and we were also, again going back to the scope of our purview, looking at what Meaningful Use had required in the 2015 certified health edition.

So balancing between those two, we really felt like we were left with a use case that had limited risk and we didn't...we felt that it was important to discuss, and in 6B we talk about that providers don't have

that obligation to protect patients by reviewing these suspicious Apps. But they certainly have the right to protect their system. So trying to balance somewhat that sensitivity between what is the provider's liability to vet these Apps versus what is the provider's right when they actually do see something that looks like it's going a little awry.

So I appreciate your comments. I'm with Josh, I feel like if we had some more time to maybe work through the...to talk through them, we could probably look at things in here that maybe some changes that would make you a little bit more comfortable. But I do think we reached the best balance of that that we potentially could have.

Paul Egerman – Businessman/Software Entrepreneur

Yeah, and I appreciate those comments and the response is, I mean in one sense I don't want to burden the providers with some additional obligation. But I do believe the provider has an obligation that says, do no harm and if they think that an App is going to harm the patient, they should block it. And that's just the way I look at it and I do not see it as reducing patient choice in any way. I mean patients still have the options they choose to to download their data and run an App off their own like desktop PC or take the data and put it in a PHR system, like Microsoft HealthVault and have the App run against that.

And in effect, that's what the Apps do anyway but the problem is, is the fact that that's what the Apps do anyway is not clearly visible to the patient. The patients do not understand that, they simply see an App that works against their physician's computer system and perhaps even think because it works against their system, if their a patient at say Kaiser and their system works with Kaiser, perhaps they assume that there is an implied endorsement by that. It wouldn't work against Kaiser...with the Kaiser system if it was bad in any way. So I think patients, you can maintain patient choice and still let the providers have that autonomy to block something they think is not beneficial.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

We have a lot of comments, umm...

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Yes, let's move on.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So let's continue to go through. We do have time to go through substantive discussion, but I have a feeling this is going to get very sensitive, very quickly. So we're going to just in order we're going to go to Kathy, Leslie, Anjum, Rich, Eric...anybody I'm leaving...oh, and Anne, sorry. So let's put...insert Ann here, so Kathy, Leslie, Anne, Anjum, Rich and Eric; starting with you Kathy.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Yeah, so thank you and I'm really going to follow on some of the earlier comments and I think that what I'm hearing within the group is an effort to try and, as you've described, set the right balance. And perhaps just as a preliminary informational item or question, it sounds in reading through the report, that there was a great deal of testimony that received from consumers who said, we want the data and we want access to it; which I don't think anyone in this room would disagree without all. So I think what we're really talking about is, does the information, does the health information go directly to the App developer or does it go through the patient and then go on to the App developer?

And the use case that I can envision or the circumstance, is the one in which there is information in my electronic health record which I have not previously viewed myself; I actually don't know what it says about me or about my health or anything else. If the information goes through me, and then goes to the App developer, then I at least then have the opportunity to do that look at and be able to say, the view and then be able to reaffirm that I want that information to go to another party other than those taking care of me for my health.

So did any such model along those lines come up or was it even con...because we've talked about this twice now and what I'm...the committee is clearly concerned. But I'm almost sensing that the testimony received, perhaps did not raise this concern and that that's why this concern is now being addressed and has not really heretofore been tackled in quite this way.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So thanks for the question and for the comments. So first of all I should say that our charge in this committee was to look at application programming interfaces for sharing data with patient selected Apps. And that is to say there's an implication of a certain workflow by which the App can request and receive data on a patient's behalf. And a lot of this comes down to simple usability. It's not clear to me completely what you mean when say that the information would go through the patient, but I understand it involves a step of review, and then...but what's not clear is once that review was performed, how does the data actually then make it to the App? And essentially that's...

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

The patient...it would be that the patient then sends it themselves to the App.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Right.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

So it's the patient reviews it before it goes further.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Got it, so what you're describing is a model of sharing, not API based, but simply based on a patient reviewing the data online and then maybe copying it from somewhere and then pasting it or uploading it into a patient facing application. And I mean those are all things that are possible with today's world of portals; you can sign into a portal, you can copy information from there, you can paste it into your own tools. The issue is it doesn't work very well. It's hard to optimize a workflow like that where a patient has to be in charge of taking many proactive steps along the way.

And maybe it's helpful just provide an analogy, and I know this is fraught, but an analogy with the financial world, where I may want to share my financial records with a site like Mint.com that's going to aggregate them, just the same way I may want to share my healthcare records with a personal health record system. And one of the real benefits to me of using a site like Mint.com is that I don't need to carefully review and approve every transaction. You know, Mint can actually aggregate them and then show me summary reviews that I find helpful because they help me, you know plan budgets.

The claim is not that patients should be coerced into sharing data this way, but simply that there should be an opportunity to have a friendly, usable workflow for making those sharing decisions. And as a patient with ecosystem that we've proposed here and that we've described, I always have the opportunity to approve a one-time access. So the only thing the App can get is what I've already seen and reviewed. And I say, okay, I'm going to approve the App to synchronize once and that's it. On the other hand, we also say the patient should have the opportunity to create a long-term connection if that's what they want to do.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

So...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

We're going to keep to the queue and just because we have a lot of comments in the queue. Actually, Leslie you are up next, so you're okay.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I'd like to build on that a little bit. Perhaps...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Just in terms of order, I think Kathy wanted to conclude her comments and then we'll go to you.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

Okay, right. So just one sort of meta view that relates to this whole; I think some of the readiness and the level of comfort that has developed that surrounds the sharing of health information data, is perhaps because we now have a model of insurance in this country that does not allow discrimination based on one's health conditions, okay? We used to and people hid lots and lots of stuff, but...and I can attest my patient's told me what to hide.

But I think there needs to be some acknowledgment of the fact that there are other uses of that health information, including in the insurance industry, that do allow there to be discrimination you might say, on the basis of pre-existing health conditions and things like that. So that's part of my concern is are we going too broad and that's my last comment.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great, Leslie over to you for what I assume will be some additive comments.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Yeah, so I think that these comments and the caution, actually we discussed a lot of this and heard a lot from people about both comments and concerns and got to this balance. You know we have view, download and transmit today, so we in effect have the ability for every patient to look at their record and their common clinical data set today and be fluent in that before making any decisions about where their data goes. It is that same use case, so it's not an expansive amount of data; it's what the patient already has access to to make those decisions. And I think that helps to mitigate some of those concerns.

Additionally, because the patients are able to choose, based upon the App they select, how as Josh says, whether it's one time, whether it's over time, how much data; it also gives more control for the patient. But we heard over and over again that the patient's choice were important and it can appear quite scary; however today we have patients making very complex decisions, health decisions that require education and understanding and are brought up to the challenge through good education, good materials, good conversations with their providers, every day. So I chafe a bit at the idea we can't be taught about privacy and use of data and I think that yes in fact we can.

The sharing of this information to my...to the App of my choice directly by me is the patient is important because without that kind of direct interaction, then the burden of taking that information, downloading it, uploading it to some new App becomes all mine and the data continuity and opportunity for error gets fragmented every time you disassociate that and make that one more removed. So this way the provider knows that what is being shared is what they have and not necessarily something else, so the accuracy of the data goes up.

So I think this group did discuss a lot of this and came to this balance because there are many people who say, "I want data, it's mine, I want access to it and I want to choose how it's used." Back to the Mint analogy, if each one of us wanted...had to re-enter information from our Wells Fargo account to our Mint.com to our IRS account, the opportunity for error, the opportunity for just overwhelming workflow becomes very difficult; so there has to be a balance.

Now with the process in this scope that includes the patient coming online to their portal of their provider, the provider has an opportunity to take that moment in time to educate that patient about privacy practices, about use, perhaps even to offer words of encouragement or endorsement on Apps they choose, that they like. But it shouldn't be a precursor to selection only...for the patient only to choose those that the provider endorses. But there is an opportunity for education because that deliberate step has to take place between the patient and the portal to actually activate the API registration to the App.

So there are moments in time to educate, there are moments in time to turn off when something is providing harm, but there is significant pushback by consumers to say, please don't patronize me, give me an opportunity to make these choices; it is mine to choose. And as a port of entry into medicine by seeing your own record, if that's filtered or distributed based upon someone else's idea of what is beneficial or harmful to me, that just seems to be against the basic right of knowing what I have, how I can use it and how I can co-produce health with others.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So again I'm going to take a little bit of Chair's privilege here and remind the committees' number one that this appears to have some level of energy behind it, but also remind the committees that there are two very legitimate and reasonable policy preferences. One being the very legitimate reasonable policy preference that I as a patient should be able to use the App of my choice to interact with healthcare and number two the policy preference that I as a provider organization have a special role to play to protect the patients that I serve and so let's just take the time to remind each other that the other perspectives are legitimate, valid and reasonable.

Number two, with respect to APIs, I do also want to remind the committees that the horse that maybe some of us are worried about is already out of the barn with respect to certification requirements and to

the requirements by CMS for Meaningful Use relative to API access to the App of the patient's choice. And that the charge for the task force was to put...was to make recommendations relative to technical and policy gates around maybe the pasture land that the horse is already roaming in, to overly extend that metaphor. So with that additional metaphor some...

M

...beat a dead horse.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

...thank you. I'm going to go to Anne.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

This is Michelle, I just want to make a comment for the public, the web room server has gone down, so for those that are following along at home, there's nothing to follow along too; but that's okay because there's no slides, you can take the time to read the report. But I just want to let you all know that we're working on it and hopefully it will be up soon. Thank you.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

So in the essence of time let me just say, I support Paul's nervousness, Paul's concerns and Kathy's point that we're far more comfortable as providers in enabling patients with their own data. I never heard any of the providers say; we wanted to filter it. So I'll take exception to that, Leslie. I think we want to do the same thing and the right thing. What I didn't see, and perhaps I missed was a mechanism for providers to say no, we don't agree with this action.

Even in medical care we happen against medical advice, but I saw nothing to be able to tell the patient, I don't agree with what this Apps going to do for you. And I think that's an important mechanism so on, I think it was page 11, I saw the patient being enabled, which is...I highly support, a simple way for them to report without having maneuver mechanics. I think providers and others legal guardians need the same rights. And if I missed it, if you'd point it out, that would be great.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure, yeah, let me just draw your attention to page 18 of our recommendations, so 3A and in particular the second bullet point there where we do describe the opportunity for providers to display a warning and request extra confirmation. So the notion is that if...before a provider lets a patient approve an App, a provider has a place and a time to say why they may disagree with this particular choice and why the patient may want to reconsider. So we absolutely do bake in that concept and we don't think that providers are necessarily required to present a well-balanced argument at that point, but providers certainly have the opportunity to, if they want to take up that responsibility.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

I think that that's a start; I don't know that it goes as far as what I was asking for.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So just to dig in on this point, I think the phrasing that you used was like against medical advice; it seems like that would be a place where a provider could say exactly that, this goes against our medical advice. Can you clarify what the gap would be?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Well, going back to I think a little bit of Paul's concern, not to speak for him but I'll speak for myself; I don't see any way that that, I can tell a patient I don't agree with this, but I'm not reporting that application for my concerns. So I think there's a protective oversight the medical community also has to help the patient have no harm come to them. And so I'm...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And can I ask a question here?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

Yes.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Are you concerned about the App that you've never seen before or are you concerned more about the App that you already believe to be bad?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

I'm...I think I'm more concerned about the App I believe to be bad, and probably one that's doing more than just receiving information and making it visual...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health

... something that actually is moving beyond that; does that make sense?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, thanks. Yeah. All right, so next in our queue is Anjum.

Anjum Khurshid, PhD, MPAff, MBBS – Senior Health Systems Strategist – Louisiana Public Health Institute

Thank you and thank you for the presentation. I really enjoyed reading the report; I thought it was very systematically describing some of the options we have. My comment is on your recommendation 6A, which is on page 28 which talks about ONC clarifying that it is inappropriate for API providers to set limitations on what a patient authorized App can do with data downstream. And so while I think from a workflow perspective maybe you have described in this three parties, you know patient, API provider and the API; in some ways the providers and patients are...we consider them part of the team in terms of having the same goals and outcomes. And providers do play a role as advocates of patients as well.

So my question is from a policy perspective, would you think it's too constrictive then to prevent providers from setting any limitations that may say that downstream you may not use this data for X, Y or Z purpose, which they consider may harm the patient. And if not, so then are you recommending some other way in which providers can contribute to that thinking from the point of view of patient as, you know protecting the patient's rights?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure, so the general framework by which we arrived at these recommendations was number one protecting a patient's rights to access, while number two, protecting a provider that wants to guide a patient appropriately. And the way that we squared this was by saying that a patient has a right to access and that a provider has a right to educate and to warn. Within that framework, I mean let's look at a couple of gray areas, just to sort of raise a few interesting questions, right?

So a provider sees that a patient is requesting access using an App from the hospital across town to seek a second opinion. It's sort of an interesting thing where yes the patient and the provider are on the same team, and yet maybe the patient wants to seek an outside opinion some place where the provider may disagree. In a case like that, it seems clear enough that it's still a patient's right to seek that opinion and the provider probably should be encouraging that behavior, but you could start to imagine a slippery slope here as we begin walk across many different use cases.

And at the end of the day, the conversation that a patient has with an App falls outside of the walls of the provider organization. The provider may not even know what the App is going to recommend, and shouldn't have to in order for these data to flow. So this was the best way that we're able to square those two or balance these two competing rights and obligations.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Great and I'd also remind people that with respect to patient right for access under HIPPA, there is no provider limitation that's allowable under that patient access; you can't limit the patient to use the data in certain ways or in other ways; the patient has a right under HIPPA for access. Okay, we're going to go to Rich.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So excellent, excellent work; I think, you know as Arien said, the horse is out of the barn and having some clarity around how we proceed forward I think is really important and I think you've given us a really good framework for that. I'd want to say that I do agree with Paul that I believe providers should have the ability to decline to provide access to an App, but I believe that's an issue, not with this task force, but with the OCR recommendations and guidance which say that providers should... if it's subject to technical feasibility and security, should provide that access.

So, there are other paths, as Kathleen suggested, to be able to get data on a read-only basis outside of HIPPA so patients can do with it as they may. And so I think there are solutions to that problem that would allow providers to avoid being put, maybe not just in a position of offering...doing something against their own best judgment, but actually creating some liability for themselves that I think is concerning. So, that's kind of on the policy front.

I wanted to suggest or ask you to consider strengthening, in two respects, the recommendations that relate to kind of the authentication of Apps where you basically say, that it's...or it should be a standards based mechanisms like OAuth 2 client. And I think where we tend to fall down as an industry where we offer optionality in trying to generalize, and I think if we could strengthen that to say, you know maybe at least for this iteration that it is OAuth 2, and we have one way of doing that, that that would be a good clarification.

And then secondly, there is a reference to Meaningful Use 2, identity proofing as if that is an agreed-upon standard for identity proofing. We had this conversation the last time you presented. But I think that you should again strengthen that; in this case I think it's up to I think ONC or may...I'm not sure who it's up to; we need to have greater clarity about identity proofing ought to be performed. Right now there are one-off ways in which that is happening around the industry and I think that our ability to have some confidence in you are who you say you are, as you're trying to use an App in connection with your information at a health system will be improved by better understanding of how identity proofing is performed.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So, umm...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

I should say first off, thanks for the comments. With respect to the particular notion around OAuth 2, I just want to highlight the fact that our workgroup explicitly left out of scope trying to make technical decisions around the requirements for specific protocols. And in part it's simply because of the composition of our workgroup. It wasn't a workgroup of engineers and technical the folks to make these decisions and in part because we were asked to look at the security and the privacy properties of these systems; we weren't asked to recommend specific technologies there.

Looking in terms of the scope that we have for Meaningful Use Stage 3, the ONC certification criteria were very clear on this point. They laid out a functional set of requirements for APIs; so in other words they describe what the APIs had to do. But the certification criteria were very clear the vendors could use any technology they wanted to achieve that, any data models, any authorization specifications; and we didn't want to interfere with the process that has been laid out there in certification.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So we have three more comments and then we're going to have voting. I can already predict that we'll have a little follow on with respect to voting. I have a preference that we, anyway, we'll get to the preferences in terms of the voting process, but let's quickly get through comments. And I'd ask at this point, if it's a rehash of a topic that's already been discussed, maybe to state an opinion and keep the comments moving. But if you've got additional nuance then feel free, but I do want to reserve some time for voting and some subsequent follow through. Eric, you're next.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects

So two comments; I'll be brief. The first is regarding voting. This is a very substantial and impressive piece of work; it's basically the technical and, well to some degree technical and policy framework that one might have expected would have been in the actual ONC regulation. Given its complexity and the recency with which it was distributed to the committees, I want to propose that we not vote on it today, that we postpone voting until our next meetings so that the committee members have more time to digest and reflect on its contents.

The second comment I had was simply to echo what Leslie said; I'm a practicing physician, in fact it's in that capacity that I serve on this committee. I today often get requests for my patients to release their records to people, not always licensed professionals, but people who in my opinion don't have a scientific approach to health and healthcare and I feel that the patients may be making an unwise decision by taking their advice and I still give them their records because it's their right. And I also will

share my opinion freely, but I think the idea of withholding the ability to transfer data from an EHR to an App of the patients choosing at the provider's discretion is a bad idea.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay. Carolyn?

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Thank you, I have two comments and a question. First to Leslie's point about patients being able to develop literacy skills and the importance of not saying, well, they can't understand so we'll take this other action. I absolutely do agree with that. We see it quite a bit in oncology with patients who are treated over the years and have to come to master the language of very complex care terms and drug names and protocols. Even when the underlying literacy level is fairly low or what we would consider less than ideal, people do master those terms and become quite...at taking care of their health because they do so. If it's helpful for the committee, I'd be happy to gather a list of references and journal articles that'll support that contention.

Second, with regard to Josh's point about the discussion about how patients can interact with Apps and the providers not aware and this might be a concern. Patients interact with all sorts of other providers all the time that their doctors never know about through what we used to call complementary care, things like chiropractic, massage, acupuncture, and lots of other things, vitamin therapies; that's not to say it's a good thing, but I think trying to legislate that through guidelines it's unhelpful because it already happens anyway.

Finally my question relates to the enforceability. I think this work does a good job of laying out how ONC might work with FTC and perhaps others in terms of enforceability. I'm very interested in finding out what's been considered in terms of bringing patients and consumers into that process? Just as there is role for patients and consumers in using Apps and in having some say and some discussion with their providers about how they would use that information and what they would do and the way to go forward together, there is also a role for patients and consumers in being involved in the enforcement.

Because quite honestly, although certainly providers have a big stake in that, it is the patient who will experience the potential harms caused by using those Apps. I think we can strengthen the process greatly if we involve consumers and patients in that enforceable some way. So was anything considered or what...how can we go forward with that idea in mind?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So thanks for the comments and for the questions. Yeah, when...I think when it comes to the consumer involvement in the enforcement process, all that we've described in terms of our recommendations was that ONC and other federal stakeholders should work together. I would expect that that process should indeed involve consumers, as most federal processes do, you know both through explicit recruitment of consumer representatives to the relevant committees and then also through a testimony process. So we didn't call that out explicitly in our recommendations because it was just one or two steps beyond the structures that we are recommending the federal stakeholders would set up. But I think it's a totally fair point and it's something we should do.

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

Is that something that can be added to the guidelines so that it is more explicit?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So one thing that I do want...before we...on page 11, I think it's the third bullet of the second recommendation, maybe that is the direction that you're headed and perhaps we could include some language here. But essentially that's the role of the patient involved in the process, logging complaints, understanding what their rights are, what their obligations are and being able to affect that. Am I following you, do you think that would be...I guess my question back to you is, do you think that would be the appropriate location for what you're looking to add?

Carolyn Peterson, MBI, MS – Senior Editor – Mayo Clinic Global Business Solutions

I don't have a particular location in the document in mind, I think that while it's critical for patients and consumers to have an opportunity to log comments. I think when we look at similar processes, for example through reporting adverse effects with FDA and drugs, for consumers it's not a very clear resolution from the time I log my comment to the time that I see investigation to some actual results. I think it needs more teeth than that, to be honest.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Okay, so I think I get you, so we do mention the place for the patient's to log complaints, maybe this is just an additional scope of what that, "website" or whatever that mechanism looks like. Gotcha.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, Devin?

Devin M. Mann, MD, MS – Assistant Professor, Associate Chief Medical Information Officer for Innovation and Population Health – Boston University School of Medicine

Thanks. I have actually a pretty specific I guess clarification because I don't think I fully appreciate the nuance of the point you guys keep coming back to that Paul raised and I really appreciate him raising that. So is the recommendation then that there should be no ability for the provider to reject access, I guess let's leave it at that versus, I mean they have this opportunity to counsel, using that page. There's always the opportunity to view, download and transmit, which so there's always access, that's not really on the table here.

But in terms of the request from the outside application into their API, the recommendation's to not give them that ability to do that? And if so, because you made the comparison to the financial industry where I do think there's a different level of...expectation when I request my financial information from Chase and want to give it to Betterman.com, versus when I request my information for my healthcare provider; there's a personal relationship that's there. And so I just want to know is the recommendation before we vote?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So ultimately the recommendation is, we are asking for clear guidance from ONC to work with the relevant agencies, realizing that that's going to bring in FTC, FDA depending on the type of App that it is, to talk about that exact thing. So first and foremost, that is the recommendation for clearer guidance. But then within that, and that's 6B on page 28, but within that we do talk about the providers obligation versus the providers right and we introduce the concept of a risk-based type of an evaluation.

So there's a difference between, if the provider is aware that an App has faulty clinical decision support, for example, and it will harm the patient. Number one, that App very well may be a medical device

regulated by the FDA anyway. But number two, that's a much higher threshold right, that would require provider intervention than if it recommends a clinical pathway that perhaps isn't a one followed by my practice or one that I would prefer that the patient choose; that's much lower risk to the patient's safety.

And, you know maybe that's something that we could see come out of that clarity and that guidance that says, you know if this is a lower risk issue that you have with this App and if you just disagree with where it ends up versus causing patient safety, then provider we don't expect you to weigh in on that. And that's, you know where we start seeing the data blocking discussion coming in, right?

So if this is clearly a safety issue and you want to suspend the App, obviously we don't want that to be a data blocking issue. But if you are dealing with an App that maybe just has a different set of recommendations than you would prefer and you want to block the patient from doing that, those are the types of actors that we would agree, you know could potentially tip that balance a little bit more toward data blocking.

So again, first and foremost, we really are asking for clarity around here and I think a few of the statements that we talk about this being a risk-based approach and provider obligations versus provider rights relevant to suspending the Apps, I think that we could...Arien to the point of how we're going to reconcile this, I think that we are trying to articulate that balance. We don't have the answers and maybe this is one of the focuses of wordsmithing, if you will that we could put some energy into to come up with something that maybe is a little bit more palatable.

Devin M. Mann, MD, MS – Assistant Professor, Associate Chief Medical Information Officer for Innovation and Population Health – Boston University School of Medicine

Yeah that's very helpful and I think it may just be a wordsmithing issue. But, you know when I thought of the against medical advice, I mean the reality is in outpatient practice often if there's a difficult relationship with a patient, you know the practice has the right to terminate that relationship.

And so it's not always a safety that, you know they're killing people left and right, but the reality is if there's a bad actor and it's not, it's one thing to restrict view, download, transmit, that shouldn't be, you own that data as a patient. But when you have the API, there's this implicit ongoing relationship that's going on there and if the provider feels that that relationship's bad, I just don't see...I think we should give recommendations for allow that to be explored and that we shouldn't take that off the table.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Agree, agree, thank you.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, Colonel Scott?

John S. Scott, MD – Program Director, Clinical Informatics Policy, Office of the Assistant Secretary of Defense, Health Affairs – Department of Defense

I want to just commend you again on the organization of this and the comprehensiveness; I think it's quite a good framework. But sort of the flipside of what Dr. Rose was saying and what you were just describing, there are actually a lot of places where you've left the detail of the guidance to the ONC, recommend ONC provide guidance on these points. And it's in that guidance that we are going to strike

the balance that we're talking about from the obligations, the responsibility to protect privacy with the patient's rights. You know, to what degree can the covered entity encourage its own endorsed Apps by the degree to which non-endorsed Apps have a harder certification process? Specific guidelines there are going to allow covered entities to strike the balance necessary, I think.

And then one other area that if I...I haven't given it a careful enough read yet, do you address any limitations to what parents can do sort of on behalf of their children? Because when we think about trying to educate the person using the API, that's the kind of concern I have is a parent downloading and posting on Facebook things, and the covered entities responsibility to say, thou, you know you should not do that seems like it would be a good idea. But it contradicts one of your recommendations.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So just on the last point when it comes to, who is the party actually making these control decisions? What we've said in our recommendations is that this...it comes down to who is authorized to access the data in the record. So we don't think there's any special considerations when it comes to APIs and sharing data with Apps; the same considerations that go into making an authorization determination in view or download or transmit should apply to API access as well. And that falls under recommendation 5B primarily.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, we're going to go to Brett and then we're going to think about a path forward to approving this document out, potentially with modification. So, Brett?

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System

You reference in topic three around trying to have...not have centralized certifications; understand you're trying to balance the making it open and easy for Apps without having that. At the same time you do reference back on page 13 one of the scope of uses is obviously the one of rogue Apps and I'm trying to understand how you balanced the security of avoiding the rogue Apps with the approach for just a endorsement process. I mean, many Apps will be good, it's the few rogue Apps that then, how are we limiting the risk of those, you know impacting both the consumer and the provider?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sure so, I mean the basic framework here is that any particular App, before it has access to any patient's data, needs to be approved by that patient. And at the time when the patient is making that decision whether to share data with the App or not, we think the patient has an opportunity, to not only read the Apps own privacy policy, but also to view endorsements or public statements that have been made about the App by organizations that the patient might trust. So that's the basic framework that we're working within.

And then additional layer of protection that we describe is, if an App is compromised, if it's hacked, if the provider comes learn that suddenly an App that maybe used to be trustworthy doesn't look trustworthy anymore, we did spell out a means by which a provider could turn off that access, again subject to patient control. At the end of the day, if the patient comes back and says, no, no, I'm using this App and I really do want it, our assessment was that the patient does have a right to it.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Wait, we did include thoughts around a model authorization form; so it's at the bottom of a page 17, it was a mock-up that Josh's team did. And to Arien's earlier point around leveraging the power of the provider portal as an educational point, to be able to include something that says, we don't see an endorsement for this App, so you know, buyer beware, try it at your own risk. I think that could be a very powerful outcome of trying to avoid a certification process for Apps and trying to meet that policy that says, we have low risk Apps that don't require to be certified by a full-blown ONC type certification program; allow access to those. But then let's allow some sort of trustworthiness visualization to the patient to where they can see right away whether somebody has already vetted the App or not.

Brent G. Snyder, MBA, Esq. – Chief Information Officer – Adventist Health System

Yeah, I'm as much concerned, not only the patient, but if it's trustworthy for the provider, so the provider isn't being precluded from...it can't block information so, you know and yet it doesn't have any basis to have a confidence or trust in that App, since there's no criteria per se other than the fact that the App is functioning. You know, I think it would be helpful if there was more security requirements around the App so the provider can be confident it's not going to introduce anything into its environment that puts it at risk.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

We actually did spend quite a bit of time talking about this topic and what we correlated it to is the HIPAA right to access information. So if the patient chooses to receive their...if they're exercising their HIPAA right to access their information and they tell you that they want to use this e-mail, there are very clear guidance from OCR that says, provider at some point even if they're requesting an unsecure, and I'm butchering this so forgive me, this obvious...don't, you know take this back to your attorneys, but basically it's guidance that says, you know providers you are not liable for that transmission of data in that unsecure method.

So we tried to analyze a little bit or we tried to correlate a little bit to that policy that says, you know at some point the consumer's going to ask for something from the provider in a way that the provider may not be comfortable with, and at some point that's just going to have to be okay. And then what will make it okay is, you know and we've asked for this guidance from OCR and other agencies that protect the provider, very clear guidance that says here is where you should and shouldn't be acting. But then also on the education up front, to provide that information to the patient as well; here are your rights regarding how you can access.

And to that end, don't do anything stupid with it; look for endorsements, you know look for something trustworthy, look for vetting; so we really tried to recognize that both parties, and I want say all actors within this ecosystem really need some additional...need some guidance around what their protections and what their liabilities are. So I'm not disagreeing with you, I'm absolutely agreeing with you and augmenting that we...that that was a topic of several discussions amongst the task force.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So first of all, just one clarification on that; my assumption, and maybe I've got this wrong is that an App that is behaving badly from the provider's security perspective, for example denial of service or other kinds of malicious behavior, that is a valid reason to shut down that Apps access.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Yes, that's right.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, good.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

And that provider actually has a right, an obligation to do that under the HIPPA security rule.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

We also do call out the fact that anyone on the Internet can play these attacks against the provider, whether it's not an App...whether or not it's an App that is registered, and so the provider system actually does need to be robust to those kinds of attacks.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So I want to frame up, you know, we've got a very long report and the discussion has been confined to one specific part of that report, which leads me to indicate that the rest of the report is fine and we've got one particular policy issue that we need to discuss and get clarity on.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

I don't think that's a fair assumption.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, what's...what are the other...so the framing of the portion of the document, and I don't mean like the specific words that...the issue at hand is relating to the providers desire to protect patients by providing applications that are in the benefit of the patient and the patient's desire to use the App of their choice in ways of their choice, to do whatever the App wants to do, that the patient has designated seems to be the central issue. Okay?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

I wouldn't frame it that way.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So I'll try to frame on the side of the concern which is, lacking any kind of fall back consumer protection body, then the proscription of anybody intervening, like the provider intervening, I mean...so basically the recommendation is that providers have no choice but to connect anything that...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

That's right.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

...technically. And the concern is not trying to be paternalistic, the concern is how do you act, as Anjum said, providers are patient advocates as well.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yeah.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So they seem...they need to have tools and if there's...if there was...so the provider doesn't have to act let's say because there are airbag safety rules. So we don't have to worry about that. In the Mint case, Wells Far...I mean Mint works because the banking industry is also regulated so that nobody has to intervene and say, that bank has reserves that are safe, etcetera.

So I think the concern here is that, there is a proscription on a federal protection, whether it's through required disclosures, and an FTC backing; there's a proscription on a federal protection mechanism and then a proscription on the provider trying to intervene as the patient's advocate. That combination, I think is what concerns...and I invite the other folks who have spoken in that vein.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And I fully acknowledge that I'm not framing up one portion of this well. I would, I believe that we could put together a motion to revise this document in ways that would be more aligned with Paul and Paul and I would suspect if we did so, there would be, and I don't know if it's a majority or a large minority that would vote no on that edit. I suspect that the document as it's currently constituted would...there's a group, I don't know again if it's a majority or a minority that would vote no, on that formulation.

We could try the exercise of doing the formulation one side and the, and you know as it currently stands and see how many votes it gets. I'd suspect that that's not a good path forward, because regardless we're going to have a, and again, regardless of what side it is, there'll be a large and I think impassioned minority that will be opposed to that report out. I...there's a possibility that I want to throw out to the group that with additional deliberation, we can find a consensus formulation, one that equally acknowledges the patient's desire to use the App of their choice and the providers desire to serve as the patient advocate.

Or we can suggest a modification to acknowledge the debate and pass it back to ONC to convene with OCR, CMS and other stakeholders to adjudicate that debate. I guess I'd remind people that the policy formulation that the task force put together is not a novel policy framework, it actually already adheres to the stated policy preferences of CMS and OCR. So I suspect if we went that direction, we'd probably end up in more or less the same place.

But I want to throw that out because we have one approach here, which is to say we can't pass this thing out because either way we're going to get a strong and impassioned minority and it's just not going to be a terribly appropriate outcome for the Federal Advisory Committee. We could throw it back to see if we can adjudicate this better. Or we can pass it back out acknowledging the significant debate on this issue and getting ONC, OCR and other stakeholders to adjudicate it. Just wanted to get a sense for the...sense of the committees relative to which of those outcomes we would prefer at this point. And maybe just get a quick show of hands for throw it back and adjudicate this particular issue.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Wait, when you say throw it back, do you mean throw it back...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I mean throw it back to you guys.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So I just want to say, you know from the perspective of our task force, we deliberated deeply, we had many conversations, and the report that we're showing you on this central question really does reflect our consensus. There are certainly ways we could nuance a phrase, or some of the language here and there, but when it comes to the fundamental question of whether a patient can say like yes I want to choose this App and provider can say no, too bad. I don't think we're going to be able to produce a report for you that changes that fundamental part of the recommendation.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yup and that would be my suspicion as well. So...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

So we don't want it thrown back on those terms. On other terms, maybe?\

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And I guess the request would be to find a model that better reflects the desire of healthcare organizations to serve as patient advocates and prevent active harm. That might be the request on being thrown back. And it might be again that you're telling us that, yeah, we've considered all of that and we're still going to present you back the recommendations that we're presenting. If you feel like you've already got the appropriate balance in place to prevent active patient harm, then that would probably be the answer that you'd give back.

Paul Egerman – Businessman/Software Entrepreneur

So Arien...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yes.

Paul Egerman – Businessman/Software Entrepreneur

In my view, making the task force do more work is sort of like punishing them for the good work that they've done so far.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yes.

Paul Egerman – Businessman/Software Entrepreneur

I mean I just don't think, I mean it seems like they've done this and this is their result.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right.

Paul Egerman – Businessman/Software Entrepreneur

And, you know my two cents is we should vote, I think the fact that there's disagreement is by itself, valuable information for ONC.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right, so my....

Paul Eggerman – Businessman/Software Entrepreneur

So I don't think we have to be unanimous, I think we should say, this is it, there was a spirited discussion, here's the spirited discussion and what the thoughts were.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right, in one version of that we can have that debate and we can go through and this piece of information, this recommendation can fail; in which case we would fail to provide recommendations to ONC. We could try it. I guess we could try the experiment, call for votes, see if we've got a majority in favor, and if we don't, then, you know ONC doesn't have recommendations.

I was looking potentially for a modification that clearly documents an alternative position and documents the sense of the task force, but also strongly documents the contrary sense so that we could pass it back on with clear reflection of the spirited and substantive debated issue. Kathy you had a...

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

Yes, so just to focus people's attention and to maybe try and help navigate through this. If we look at 6B and we look at the language that's in there, there is an indication that the provider may suspend access to an App that had breached the provider's terms of service, or appears to have been compromised, or if the App poses a threat to the providers own system.

If we then say, the next sentence then addresses the issue of overrides, of when can...when is there a legitimate override? And it says that, the overrides are allowed and it's in parentheses except in the case where the App poses a threat to the providers own system, so that mirrors the language above...or violates allowable terms of service, so that mirrors again the language above. The section about appears to have been compromised is not mirrored in that. So one of the things that I would suggest is that there be a replication of those three elements; that would take care of, I think one concern.

If we get to the bigger concern which is if we think it is an App that hasn't done all those things, okay, so it still remains shall we say an unblocked App. But there is a concern on the part of the provider about that App, so it may not have bubbled up to a full-blown, you know, major health information security issue. Then there are a couple of ways through this; one would be to say, that that App that's being blocked goes out with, or that the patient gets guaranteed notification, we have concerns about this App for the following reasons, the following criteria that we are raising.

It gets you back to the recommendation from...about the Department of Defense criteria, and this is in 3B. And it says for example the DOD, it's the only bullet point, may create a list of criteria by which Apps that access the EHR data of active military would need, I think there are some extra words in there, would need to indicate the Apps trustworthiness. So it's a complicated workaround, but if there are criteria such as those suggested that are DOD criteria, and have been adopted through let's say subsequent work performed by either this task force or another task force, could that then become legitimate reason, failure to meet those criteria, that have been vetted, become a reason to block the App?

M

There is the whole point; I think there's adequate room for that type of clarity to protect what you're talking about.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

But...no.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Kathy, I thought you were going in a different direction which is if you look at 3A, one of the task force recommendation already note the ability to provide a warning to the App, but the suggestion is just if the App is not certified. There are cases where the provider organization believes the App is fishy, squirrely, wrongheaded, not justified by evidence; I think the task force would believe that the provider organization would have every reason to present a warning to the patient that, you know this App does not present known good evidence and in fact is wrong on all counts.

There's an example that Chrissy Farr gave in Fast Company of a bipolar decision support App that suggested drinking during manic episodes. And, again I think it would be legitimate for provider organization to say, no, no, this one is bad. With respect to the example of an App that has not passed say a cross federal partnership for certification, I guess there are reasons and then there are reasons, right? So if the App is not based on good evidence, but isn't doing anything malicious or untoward, is it appropriate for the provider organization to block that App or is it more appropriate for the provider organization to present a significant warning?

M

Or how many obstacles can be put in the way of using it?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Right, that's right.

Kathleen Blake, MD, MPH – Vice President – AMA-Convened Physician Consortium for Performance Improvement – American Medical Association

So I'm trying to navigate the fact that we're, and I am very respectful of the fact that we don't want paternalism, at the same time we want to also have patient safety. So if there's an agreed-upon list, the criteria that are proposed in 3B, that then, if access is blocked that it would, for example, have to include or be on the basis of one of those criteria for what we would call here I think good word, trustworthiness. So you can't just block it for anything, you have to block it because it did not meet criteria from that list.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Can I ask for clarification there because trustworthiness could mean two different things; one is, trustworthiness could mean the App is sending data to China or some other nefarious organization. The other could be, you know the App provides decision support based on astrology. And...

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

So I would imagine that that list would include both; it would say, we know that information is going to China...

M

There's disagreement.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yeah.

Kathleen Blake, MD, MPH – Vice President – AMA-Convended Physician Consortium for Performance Improvement – American Medical Association

...but it could also say, it's not trustworthy because it's based on astrology; so something could be blocked on either basis.

M

Why don't you let other...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I'm trying to still forge a consensus point here.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

We explored a half a dozen facets of trustworthiness at the beginning of topic three on page 16; and this was not meant to be an exhaustive list, but we talked about clinical trustworthiness, privacy related, security-related, value for money, stability, reputation and you know there's probably others. It seemed pretty clear in the context of a framework like this that trying to lay out a set of criteria by which you would make a black and white judgment call about which Apps the patient could and couldn't use, was going to be an exceptionally difficult proposition, which is why what we fell back to in the end was, shared decision-making with the patient, advising but letting the patient make the ultimate call.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

And I also want to point out that the issues that something like that would present to the App registration process and including the providers obligation to vet that App before access is allowed, and that was one of the things that we were very clear upon that this should be an easy connection that should not require the providers to vet the App themselves or be any part of that certification process.

So while I'm certainly not arguing against your suggestion, I'm just...I'm clarifying that I think that the discussions amongst the group is that it would be important that we didn't add any provider liability or obligation for them to vet any of these Apps before connectivity. I think it's fair to note when there is no endorsement, but our comment around the DOD providing an endorsement criteria was a suggestion and leveraging the powers that be of the government as an agency to be one of the ones that provide that endorsement criteria. But we hadn't anticipated that that would be something that would then be rolled out at scale for any other populations other than in our example, use the DOD and the active military. We, I think we previously had an example around AARP having one for elderly or something like that; it's going to be very specific to that population and I think we would be hard-pressed to find an endorsement certification criteria or endorsement, to your point the best practice for what this

endorsement looks like that would be able to be rolled out for all Apps of all types of accesses and functions.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So we're short on time and if we're going to vote, we need to vote. I would suggest and I want to see if the task force would disagree, that a sub-bullet for 3A, would acknowledge a provider organizations ability to present fair warning for an App that is known not meet one of the criteria listed previously. So it's different from doesn't have an endorsement, but you know this App is based on astrology, this is not sound science and we therefore strongly encourage you not to use this App.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

That's entirely consistent with what we were expecting the provider could do.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And then I'm going to try this out, and you guys are speaking for the task force, but would a reason to block an App be that the App does not adhere to known good privacy and security guidelines where those privacy and security guidelines are bootstrapped to some future convening approach?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...the patient to determine what's private and not. And if the patient says, you know what, I'm involved in a research trial and it's not going to be in the US, it's going to be in China and I want to be a part of that, that's just because it's the patient's right.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, so what I'm hearing is an accepted amendment where providers have every right and obligation, every right at least...

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Right.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

...every right to supply fair warning for an App that they deem known bad and require, in the examples that you gave, require the patient to affirm that they've read that guidance and are proceeding nonetheless. So with that amendment, I would like to, we'll follow the Policy Committee's Roberts Rules approach here.

M

Can I...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yes.

M

...again. So I'm not sure that amendment is necessary. It seems like that amendment...that functionality is amply provided for in the recommendations as written.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

But it's a friendly amendment and I don't think it..,

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

It clarifies.

M

If it makes people felt better, it's fine.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yeah, it clarifies the affirmative role the provider organizations have. So with that amendment...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

...exercise.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

With that amendment, I'd like to ask for a motion to approve the recommendations.

P. Jonathan White, MD – Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Who will dare?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Who will move to approve the recommendation?

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Can I?

Donna R. Cryer, JD – Founder and President – Global Liver Institute

I so move; this is Donna Cryer.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, it is both moved and seconded. So at this point, all in favor please raise your hand. Okay. People on the phone, who on the phone votes to approve?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I see that Kevin Johnson and Donna Cryer have approved on the phone.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay.

Gayle Harrell, MA – Florida State Representative – Florida State Legislature

And Gail Harrell does.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

And Gayle as well.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

And John Derr.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay. Who opposes?

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

John Derr approved.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay and then, there is some level of apparent, oh crap, okay. Let's go again, okay, we're going to count it, we've got to count it now. So again.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

Can I ask a clarifying question?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yup.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So earlier you said something about one of the alternatives was to refer back to ONC, the debate around this.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

We'll get there, yeah, we'll get there.

Richard Elmore, MA – President, Strategic Initiatives – Allscripts

So I'm trying to figure out what I'm voting, because I'm supportive of that...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

At this point we are voting for the recommendations as currently worded with the amendment that was suggested. So this is the document that currently exists here with the one change that there is a sub-bullet and 3A to the effect that provider organizations should have the ability to note an application that does not meet its criteria and present that to the patient prior to the patient's using that application. And you guys can wordsmith that, but that's the intent of that bullet. So again, all in favor of the recommendation please raise your hand. And then two on the phone, three in the phone?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

It was four I believe.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Four on the phone so we have 13 in favor; all opposed? How many on the phone?

Gayle Harrell, MA – Florida State Representative – Florida State Legislature

Gayle is yes.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Okay, so the ayes at this point have it by a very narrow margin. I think the level of the margin needs to be communicated in the transmittal to ONC and with that...

M

So what was the vote?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

The vote is 13 to 10.

M

So I think you're premise, your suggestion that we try to get to a little bit more consensus.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

That would be...

M

You know, I feel confused; I'm sorry. So when I listen to the issue, if I'm understanding the issue correctly, it feels as though an App can be looked at as any sort of healthcare intervention. And at the end of the day, we prescribe interventions or we have over-the-counter interventions and we have a situation, it sounds like where we have providers who want in the best interest of the patient to give guidance. And we have patients who need to have the, if you will, free will to make decisions about their health care.

But every single day, healthcare is delivered in this country in a way that providers impose a practice pattern on patients and patients either stay with that provider or they leave. And if, you know for those of us who are clinicians we say, we like these drugs or we don't like these drugs. We like to give vaccinations are we don't like to give...we are constantly, you know imposing, if you will, our beliefs and patients will go and seek different kinds of practice patterns.

So is this not very similar to that where if you have a provider that says we're going to block this App, the patient can say, well I want that App and then there are a lot of other providers they can go to to get the App or whatever kind of drugs or interventions or diagnostics...

W

Indiscernible.

M

Pardon?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

That's a reasonable, so that is a reasonable policy perspective. It is not the one that is already where OCR and CMS have already provided regulation or guidance, so. But again, I think there is a substantive and very vocal group, and probably with a different set, so I'm going to...with a different set of people

who are participating in the joint committee, we might have a slightly different vote; the yays might have it, the nays might have it.

I think...I go back to my previous position that reporting this out as having received the endorsement and approval of the committee on a narrow vote probably isn't it appropriate; not making recommendations I believe is not appropriate. And so I think the best thing to do in this course would be either have I minority report or to revise the recommendations that make it more explicit that there are two I think equally reasonable perspectives.

One that I would characterize according to Dale's comments as being the perspective that an App is more like a medication or a therapy than it is like a patient access responsibility. The other, per Leslie and a number of others that an App is something that the patient has responsibility and authority to do and this falls under OCRs guidance relative to access. And both of those I think are very reasonable policy perspectives, they just happen to be diametrically opposed.

M

I wouldn't disagree with what you said, though and I wouldn't disagree with...

M

Why don't we go through...

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

We're dangerously short of running out of time and running out of time for public comment. Andy, yeah?

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

...the full time but I just compel...feel compelled to make a brief editorial comment. If patients want to get around blocking an App, they're going to. They can get all their data in another way and put it into an App; it's cumbersome, but they're going to. This is a debate about a non-issue; it's just a debate about whether it is or isn't convenient for patients to put stuff into an App.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

That's right.

Andrew M. Wiesenthal, MD, SM – Director, Health Care Practice – Deloitte Consulting, LLP; International Health Terminology Standards Development (SNOMED)

They're...and when I was in practice, you know you ran the risk of alienating them and losing them as a patient if you block something. And I would just say, look I don't believe in the mega vitamin therapy that you're about to engage in, I don't think there's science behind that or whatever it was I didn't believe in. But I made it clear that my beliefs wouldn't interfere with my therapeutic relationship and that I really would rather know what they were doing and I wouldn't interfere with them; unless they wanted my advice, they could have it and if they didn't want my advice, they weren't going listen anyway.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Paul, it sounds like you've got an alternative pathway forward and love to hear that.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Okay, I'll give maybe the complement amendment for consideration. So the issues that got to me are the combination of there can't be any protection from a regulatory point of view and there can't be any advocacy from the provider point of view; so you gave the provider side. Let me try to propose the other way which is, I think if there were, and somebody mentioned this, if there were a list of...Kathy started this, if there was a recommendation for the criteria that Apps need to be...need to publish about let's say privacy, then that gives both better information to the consumer and it gives the FTC the...who has the authority to back that up. And that takes the provider out of the loop.

So I don't think...of the two solutions addressing the two solutions, I think getting the provider in the loop has a lot of other unintended side effects; making a regulation that has...making a recommendation that has these criteria that Apps should address, making that public, gives more...makes more information available for decision-making and invokes the authorities that the FTC has. That would be my cor...my complement.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

I'm struggling with what the amendment would be. So we've got an existing recommendation that there be a model guidance or model notice...model privacy notice. Would you then go farther than that to say that Apps must use the model privacy notice?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

So I think it's very much like the DoD recommendation is having specific criteria, not just the model privacy notice, making the, you know the recommendation would be that ONC produces this list of criteria and then the FTC would have it under its ability to enforce it if somebody does disclose it and makes wrong statements. So that does take it out of the...that takes the provider...it makes the provider more comfortable in...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

Just to clarify on that, if I may Arien take a second. So Paul your recommendation is for the endorsement criteria particular, you would like ONC...you would like the task force to recommend elements that should be contained in that endorsement criteria? One of the things that we had heard and discussed during those particular conversations was that an endorsement may be very specific to the type of App and the type of function that it performs.

And so for example your list of endorsement criteria may be specific to diabetic management versus some other thing. How would you reconcile that I guess is my question?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health
Sure.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

If the elements are not contained in the model privacy notice or in the model authorization form that we recommended and instead are endorsement criteria, I'm not sure how to cross the bridge without getting into the function.

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

Let me try not use the word endorsement, because I think that's burdened with a stronger notion than is intended. It's probably closer to the model privacy notice in the sense of these are the things...these are the checklist that every App developer needs to produce, the answers which they need to produce, so, what happens if you go bankrupt? What happens to your data if you...a list of things that would be informative for the consumer so the consumer make their independent judgment, and yet if you don't disclose that in a truthful way, then the FTC can back it up in terms of protecting the consumer.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

Sounds like...

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

So specific to the changes to this report, because we do include recommendations for the model privacy notice that includes those data elements. Again just trying to cross that bridge, would this be taking it that one step further and requiring Apps to follow that model privacy notice as part of the requirement to connect with an EHR API?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

I think it would be...like to do the voluntary but it almost would be a requirement for doing business, just like the EHR Incentive Program was voluntary, but essentially became a practice. So I'd like to get ever so close to it being a requirement for App developers to expose these things to the public so the public can make a much better informed choice.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

But if you wouldn't cross the line and make it mandatory, what would you change to our recommendations about model privacy notices?

Paul Tang, MD, MS – Vice President and Chief Health Transformation Officer – IBM Watson Health

That's what I would change.

Joshua C. Mandel, MD, SB – Research Faculty – Harvard Medical School

You would cro...you would go over that line and say it is mandatory?

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Yeah.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation

In order for...Paul, just to clarify; so in order for an App to connect to this EHR API, they would need to comply with the model privacy notice that ONC would create? Is that your statement? Okay, I'm clear on that.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Vindell, did you have anything you wanted to say?

Vindell Washington, MD – Principal Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

Yeah, I've struggled to stay quiet. I guess I would say just one overarching piece; I think it might be helpful from a framework perspective to think about it in terms of the activities without the technology and then layer in the technology for the purposes of conversation. I think it was stated a little bit earlier, some of this conversation thread has been really around what patients do with information when it's in their hands; I think you'd have a hard time arguing whether or not you'd give a patient their information even if you knew after they copied that paper record that they were going to go across the street and talk to some provider that you had a lower level of trust to.

I think when we at least had some of these discussions before, we spent a lot of time talking about the security, not the privacy, but the security that connecting that App may or may not affect. And I think that was covered in the recommendations; so if by allowing an application to connect in some way put in jeopardy the records of other patients that are in my care, that's one issue. I struggle with the concept that there's going to be a large barrier for us providing that information because I think at the end of the day, that just provides a burden for patients on the other end of that spectrum for things that us as providers would give paper records to and have a conversation that would let our thoughts be known, but not stop it information from being transferred.

I think in terms of the overarching comments that have been made and discussion points, I think we at ONC are hoping very much for a recommendation from this committee. We certainly know that it, you know like with a lot of things that are controversial, it may not be 100% agreement; it might not be complete consensus. But I would just offer that framework of thought around this information flow as you consider whether or not, what role providers should play in releasing information to patients.

And this arbitrary line between what the application does once it's added, versus access to the application in my mind at least is more of a matter of whether or not you want to burden for entry to be a manual burden of entry or not, once you've crossed those security conversations.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

So I understand that there are a number of additional cards that are up and there's a, I think a good degree of passion to continue this discussion. Unfortunately, we're at the time for public comment as well as announcements for the sequence of upcoming meetings. So Michelle, why don't I turn it over to you relative to the future calendar and to public comment?

I think the state of this recommendation is that it is narrowly approved. I don't think that is something that all of us or any of us are terribly comfortable with in the current state of discussion. So I think the Chairs will likely confer with ONC relative to the best way to proceed forward with substantive recommendations to ONC.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

I will say I know there's a number of concerns in the room so perhaps I could funnel them through me if folks want to send me some concerns that you weren't able to share here.

Arien Malec – Vice President, Clinical Solutions Strategy – RelayHealth Corporation

Perfect.

Public Comment:

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And then we can figure out with the Chairs how to follow up on those. Okay, with that, thank you so much to Josh and Meg for all your patience; I think Meg's missed her flight so we owe her a huge thank you. So, I'm sorry.

With that, if there's anyone in the room who would make -- like to make a public comment, please come up to the comment, you can please come up to the table. As a reminder, public comment is limited to three minutes. And if there is anyone on the phone, Alan is going to now open the lines for those folks.

Alan Merritt – Interactive Specialist – Altarum Institute

If you'd like to make a comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

While we wait for public comment, I just want to let you all know about sequencing of some of the meetings over the summer. So we are going to have a short virtual meeting on June 8 and then we're also going to then have another meeting in June, which is June 23. That's when the Quality Payment Program Task Force will come back and present their recommendations; so it's a really quick turnaround time for them.

And then we are working on canceling the August meeting, which is currently scheduled I believe mid-August and making that the end of July so that we'll get rid of a July and an August meeting for one meeting at the end of July. That remains to be scheduled, so please be on the lookout for that and that will also be virtual. We're trying to minimize the time that we take up in summer. There's two meetings in June, June 8 is virtual, June 23 is in person.

And it looks like we do have a public comment from Adrian. Just a reminder Adrian, your comment is limited to three minutes; please go ahead. Well I'm not sure what happened, we'll follow up with Adrian to see if she wants to send written comment. Okay, thank you everybody, we really appreciate it and have a wonderful rest of your day.

Adrian Gropper, MD – Chief Technology Officer – Patient Privacy Rights

Oh. I'm sorry...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Adrian Gropper, go-ahead Adrian.

Adrian Gropper, MD – Chief Technology Officer – Patient Privacy Rights

...the API task force doing a very di...good job on a very difficult subject. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Adrian. Okay, thank you everybody.

Public Comment Received During the Meeting:

1. Gary Dickinson: Gary Dickinson - CentriHealth - What effort is going to ensure that MACRA/MIPS does not create a greater burden on physician time spent on counting, measuring and reporting vs. time spent in actual clinical practice? Is this demonstrated in real practice settings?
2. Steven Quentzel: Steven Quentzel, GMA Consulting: What "provisions" would there be for integrating data from participants in clinicals and specifically those receiving blinded interventional therapy?
3. Gary Dickinson: Paul Egerman is right on...It's not limited risk rather it's unlimited risk.
4. Karen van Caulil: This is Karen van Caulil. I need to run the NBCH meeting in one minute. I am sorry I am unable to stay on the call to vote.

Meeting Attendance				
Name	05/17/16	04/19/16	03/10/16	01/20/16
Andrew M. Wiesenthal	X		X	X
Angela Kennedy	X			X
Anjum Khurshid	X	X	X	X
Anne Castro			X	X
Anne LeMaistre	X	X	X	X
Arien Malec	X	X	X	X
Aury Nagy				
Brent Snyder		X		
Brian Burns			X	
Carolyn Petersen	X			
Charles H. Romine	X	X	X	
Chesley Richards				
Christoph U. Lehmann	X		X	X
Christopher Ross		X		X
Dale Nordenberg	X	X	X	
David F. Kotz	X		X	X
Devin M. Mann				
Donna Cryer	X	X	X	X
Elizabeth Johnson	X		X	X
Eric Rose	X			X
Floyd Eisenberg	X	X	X	X
Gayle B. Harrell	X	X	X	

James Ferguson				
Jitin Asnaani	X		X	X
John Halamka				X
John Scott	X		X	X
John F. Derr	X	X	X	
Jon White	X		X	X
Josh C. Mandel	X	X	X	X
Karen Desalvo		X		X
Karen van Caulil	X			
Kathleen Blake	X	X	X	X
Kevin B. Johnson		X	X	
Kim Nolen	X	X	X	
Kim Schofield			X	X
Leslie Kelly Hall	X	X	X	X
Lisa Gallagher		X	X	X
Lorraine Doo	X	X	X	X
Nancy J. Orvis		X	X	X
Neal Patterson		X	X	
Patricia P. Sengstack		X	X	X
Paul Eggerman	X	X	X	X
Paul Tang	X	X	X	X
Richard Elmore			X	X
Scott Gottlieb	X		X	X
Steve H. Brown				
Troy Seagondollar		X	X	X
Wes Rishel	X	X	X	