Department of Health and Human Services

NATIONAL COMMITTEE ON

VITAL AND HEALTH STATISTICS

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P R O C E E D I N G S (8:33 a.m.)

Agenda Item: Welcome

DR. STEAD: Welcome to day two of our full committee meeting. We are all being challenged by the bugs that are going around and other challenges, so I appreciate the number of people that are joining us over the phone while we control the infection burden in the room.

I will start with roll call of the members. I am Bill Stead, Chair of the full committee, from Vanderbilt University, no conflicts.

MR. COUSSOULE: Nick Coussoule, Blue Cross/Blue Shield of Tennessee, member of the full committee, Standards Subcommittee, Privacy, Security and Confidentiality Subcommittee, and I have no conflicts.

MS. GOSS: Alix Goss with Imprado. Member of the full committee and Executive Committee and Co-Chair of the Standards Subcommittee and I have no conflicts.

MR. LANDEN: Rich Landen, member of the Full Committee, Co-Chair of the Standards Subcommittee and no conflicts.

MS. STRICKLAND: Deb Strickland, member of the Full Committee, member of the Standards Subcommittee, and I have no conflicts.

DR. PHILLIPS: Bob Phillips, Center for Professionalism and Value in Healthcare, Co-Chair of the Population Health Subcommittee and member of the Full Committee. No conflicts.

MS. HINES: On the phone?

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

MS. HINES: Lee.

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

MS. HINES: Frank.

DR. PASQUALE: Frank Pasquale, University of Maryland, member of the Full Committee and Chair of the Privacy, Confidentiality and Security Subcommittee, no conflicts.

MS. HINES: Jacki.

MS. MONSON: Jacki Monson, Sutter Health, member of the Full Committee, member of the Subcommittee on Privacy, Security and Confidentiality, no conflicts.

MS. HINES: Great. We have a quorum. Let us go to staff. Sharon Arnold, are you on the phone this morning?

DR. ARNOLD: Yes I am, thank you.

MS. HINES: Sharon Arnold is with ASPE. She is the staff director for the committee. I am Rebecca Hines, Executive Secretary, with CDC's National Center for Health Statistics. Let's go to the other staff for the committee. Rachel Seeger.

MS. SEEGER: Rachel Seeger, HHS Office for Civil Rights. I am the lead staff to the NCVHS Subcommittee on Privacy, Confidentiality and Security.

MS. HINES: We do not have any other staff in the room yet this morning, so let's do members of the audience.

MR. STRAUSS: Warren Strauss, Karna.

MR. STELLAR: Charles Stellar, WEDI.

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

MS. GORDON-NGUYEN: Marissa Gordon-Nguyen, Office for Civil Rights Privacy Division.

MS. WEIKER: Margaret Weiker, NCPDP.

MS. HINES: Okay, roll call is done.

DR. STEAD: This morning, we are going to begin with our focus on privacy and we are getting input from OCR. Then we are going to hear from the NCHS on the redesign of the Health US Data Program because they want guidance into this recasting that is underway. Then we will have a dive into the Federal Data Strategy.

In the afternoon we are going to be working on the plan going forward first for privacy and security, which will obviously be informed by this morning's conversation, and then the rest of the full committee work plan.

I really am delighted that Tim Noonan has been willing to join us. Tim is the Deputy Director for Health Information Privacy at the Office of Civil Rights. He previously served in the OCR Headquarters as Acting Associate Deputy Director for Operations, and the Acting Director for OCR's Centralized Case Management Operations. We are really appreciative. We depend on OCR's guidance in how we can best inform our work, particularly the work of the Privacy, Confidentiality and Security Subcommittee that Rachel Seeger is the lead staff on. Her engagement and the engagement of OCR have essentially been essential to what this group has done.

As you know, our responsibility in advising HHS is built into the HIPAA laws, so it has been a responsibility now for over 20 years. We know that you are sensing, and we sense just a sea change of what's going on in the approach both nationally and globally around health information privacy. So, at this juncture we are just delighted that you have been able to take the time to spin

us up. Again, thank you for Rachel's support. We clearly would be lost without it, so thank you.

Agenda Item: Briefing and Updates

MR. NOONAN: Good morning. Thank you for the invitation. I am extremely pleased to be here to share an update on what the Office for Civil Rights is doing within the Health Information Privacy Division with respect to our policy and enforcement activities. I, too, want to acknowledge Rachel Seeger. Rachel is our head of media and outreach and does a fantastic job for us and is an incredible resource as you all get to see with your interactions with her, as do we.

HIPAA has been in the news a lot lately, making her job more challenging than usual, but it is fantastic work. We are pleased with the staff that we have within OCR and the HIP Division. A lot of challenges and changing landscape, but we have great folks onboard that are extremely committed to everything that we are trying to do with the protection and security of health information privacy.

I would like to start off with policy. Also in the audience today is our head of policy, Marissa Gordon-Nguyen. If I say anything that is of interest to you and you would like to hear more, I am happy to come back at

another time and speak in greater detail. Marissa would also be happy to speak. I wish I had more time today to speak at length on everything that we are doing, and hopefully you will feel the same way when I am at the end of my discussion.

I think the first place to start within policy is that we issued a request for information last year modifying the HIPAA rules. As noted, we received over 1300 comments, close to 4,000 pages. The comments are still viewable at regulations.gov. We spent a large percentage of this year going through the comments and trying to make intelligent proposals that will ultimately be issued in a notice of proposed rulemaking on what types of modifications can be made primarily to the HIPAA privacy rule, to improve coordinated care, reduce burdens and strengthen some of the areas of concern that we have observed over the years with our enforcement program.

The privacy rule, as you know, was first written in 2000, and as I was getting ready for today's discussion I was thinking about how much things have changed since 2000 just in terms of technology. There were no iPhones, there was no Facebook, YouTube did not exist. There was no Twitter, there was no Skype, there wasn't even Wikipedia. While there have been some incredible significant changes

that we all rely upon on a daily basis, if you are like my kids you cannot remember a time when these things did not exist. The dial-up modem with the beeping noises -- they wouldn't know what that is and would be outraged if it took more than four seconds for your internet connection to go through. So a lot has changed, but significantly, for privacy, a lot has not changed.

What I would focus on in terms of highlights for the privacy rule and some of the proposed modifications are the items we have listed here, starting with the right of access. The right of access is a fundamental right to OCR. You need to know what's going on with your health, you need to be able to access your health data, you need to be able to use the health data in order to make informed medical decisions, you need to be able to pass along that health data to whomever you want, other doctors, family members, et cetera.

Over the years, OCR has supported the right of access with regulations and guidance, training. We have a Medscape module that over 70,000 people have been trained on since July of 2017. We thought it was time to take a look at the right of access and what could we do to further bolster, support and enhance patients' access to their medical records.

When the rule was written we said 30 days to get your medical records, so, in the RFI we asked questions about that. Is that still a reasonable time? Should there be a distinction between records in the electronic health record system versus records in paper? We were cognizant that in some states -- I think Texas and California -- it's a shorter period of time, 15 days, so, is there a shorter timeframe that should be observed? Should there be a distinction in the records?

And getting the feedback from a large variety of stakeholders, the covered entities and business associates that are involved in providing the right of access as well as the individuals. We have what we think are some very thoughtful changes to the privacy rule that we are anxious to share with the public and get everyone's comments on.

The second item I would highlight is addressing the opioid crisis and serious mental illness. In the past, we have issued guidance on the ability of providers to be able to share an individual's PHI when an individual is not present, is incapacitated or in an emergency circumstance. But we see in the newspapers, we hear anecdotes, we hear stories, we see complaints of instances where family members are shut out; they are not aware of what's happening with their loved one. They are not able to

participate and provide additional support for an individual that's experiencing those things.

And despite the guidance and the permissions that we have existing in the HIPAA privacy rule, we are interested in is there something more that OCR can do. We have tried to address this in the past through guidance. Is there some regulatory change in the text that we should consider to further encourage the sharing of information and getting it in the hands of the folks who can really help an individual that is suffering?

It is a challenge making these kinds of modifications. The original work was very thoughtful. There is a tight balance. Individuals with severe mental illness or undergoing an opioid crisis may not seek access to treatment if they have concerns about their information being shared without their permission, and so we want to be respectful and mindful of their interests in this situation as well as the family members'. So again, deriving a large variety of comments from various viewpoints, and I think we have something that we will be able to share next year that will really be helpful.

The last item I would focus on is Notice of Privacy Practices Acknowledgement. That is a good example of some of the deregulatory efforts we are undertaking to

reduce burden. As you know, there's a requirement to make a good faith effort to obtain a written acknowledgement of receipt of the notice and, if it is not obtained, your good faith efforts for six years. Having heard from providers that that is a significant burden, takes up a lot of their time, and seeing instances in our enforcement program where there's confusion. What happens when an individual seeking medical treatment refuses to sign the Notice of Privacy Practices? In some instances, they have been denied treatment, which was clearly not the goal in creating this regime.

So we posited the question is this serving any real utility. Is it a benefit to the consumer? Is it a benefit to the covered entities? We think we have landed in a good spot to offer some suggestions.

Earlier this year we issued a Notification of Enforcement Discretion regarding HIPAA civil money penalties. As you know, in 2009, the High-Tech Act created four penalty tiers based upon the culpability ranging from did not know, no knowledge, to willful neglect-not corrected. We issued an interim final rule in 2009 and a final rule in 2013 that set $1.5 million as the annual cap for all of the penalty tiers.

In April of this year we issued this Notification of Enforcement Discretion. The Department, as part of its regulatory work, reviewed all of the regulations that we enforced and the Department made a determination that we think the better reading of the statutory authority that Congress gave us through the High-Tech Act was that there should be distinct annual caps that are different for each culpability tier. So, as you see in the highlight on the slide, three of the tiers have had the caps changed from the $1.5 million to what's represented on the screen. The willful neglect remains unchanged with the $1.5 million cap.

OCR's resolve to continue to enforce HIPAA and seek compliance from covered entities remains unchanged, unwavering. In the last two years we have done 18 enforcement actions that have resulted in a settlement or the imposition of a civil money penalty. Nine of those actions have included a count at the willful neglect-not corrected stage, and so we believe there still are remedies and sufficient deterrents built into the statutory authority that Congress gave us to vigorously enforce HIPAA.

Also in April of this year we issued some FAQs regarding health apps and the right of access. You will

hear me talk a little bit about the right of access today. It is a continuing thread that I think connects everything that OCR is focused on this year with respect to police, to the stuff we have issued in guidance as well as our enforcement priorities.

The health app FAQ -- We had worked with ONC and we had heard some anecdotes and information about confusion and concerns by covered entities with respect to the sharing of individuals' records with these third-party apps, so the FAQ focused on the relationships between the health record system, the covered entity, whether it is a business-associate relationship, and the consumer.

Three main takeaways that we wanted to emphasize were that a covered entity cannot withhold releasing ePHI to a user-requested health app because of concerns about how the app will use the ePHI -- the idea of benevolent paternalism. The covered entity is concerned that the individual may not fully understand their actions or what it is that this third party is going to do with their data, but the right of access gives the consumer the right to their records and to direct them to anyone they want, including a health app. And so it is not a basis to object or refuse to provide an individual with access to their records.

Point two is a corollary to that. If we are going to say that a covered entity has to provide the records through an app that is a third party, they are not liable for any re-disclosure of the ePHI by the health app if there is no business-associate relationship.

Item three I think fits nicely with the Beyond HIPAA report that this committee put together and it's something that we are interested in sharing and making sure consumers are fully aware. The HIPAA rules don't follow health data everywhere it goes. That is one of the key significant challenges. You have seen all the activity on the Hill. OCR is also very concerned that, as the data moves, sometimes it is protected, sometimes it is not. Is that fully well understood by the consumer, and what can OCR do to make sure that the consumer fully understands what can occur when they use these health apps that are not within the HIPAA landscape?

It reminds me, I read a book last year, and I apologize, I don't remember the title, but I liked the way the author framed it. I thought it brought clarity to this infusion of apps that we have available in our resources. "If the app is free, the product is you." We love our apps. You get them on your phone. It tells you it needs access to all this stuff. We hit yes, yes, next, next, as soon as we

can without thinking about it. If they are offering it for free, it’s because they are tracking you. They want to know your daily decisions.

The world has changed so much. Even the concept of memory. Our ability to remember has changed because now we have resources -- email, Twitter. We have a complete record. So your memory of something you said or did last year is no longer a hazy memory that perhaps is how you best remember it. You can actually pull up documentation of what occurred. As we see the technology evolve and the free flowing of information, I think everybody has to recalibrate their minds to understand the significance of that.

The health app FAQs was our first step in that foray, and we would anticipate working closely with ONC to continue to develop products to educate consumers as well as the industry on the sharing of information, the benefits and the potential perils.

Lastly within policy, I want to talk a little bit about surprise billing. The President issued an executive order asking us to take a look at the surprise billing issue. Many people have had the situation where you get the medical bill at the end of a planned procedure and there’s a radiologist or anesthesiologist that is out of network.

You really didn’t have a role in selecting the radiologist or anesthesiologist but now you have a significantly higher bill than what you anticipated. So, what can we do to address that?

We held listening sessions with a variety of stakeholders to try and understand their perspective on the problem and, also, what can be done to get that information to the consumer so that they have an awareness of what the planned procedure is going to cost.

An emergency situation probably creates more of a difficult challenge. When you’re in the ambulance you don’t have the faculties or the ability to enter into a lengthy debate about what the radiologist’s participation is with various insurance companies. But what can be done? We have the right of access within the designated record set, and in the definition of individually identifiable health information there are tools that can be used to try and develop something where consumers could have access to future billing before it occurs and have an opportunity to make more informed decisions.

We are at the very early stages of this. We are still gathering information and hope to put out something next year to get feedback. We will need a lot of assistance on this. It’s a challenging problem, there are a lot of

hands that touch the steering wheel, so it's something that will be part of our focus for next year in the policy area.

Next, I thought I would share a little information about our recent enforcement activity. Serena Mosley-Day is our head of HIPAA enforcement. She does a fantastic job of working with the regions. We have eight regional offices and that is where all the investigations occur. The HIP Division works very closely with the regions to identify potential cases for enforcement and try to identify themes and messages that we think are important for the industry to understand. Under Serena's leadership we had a record year last year of collections of over $28 million as well as the single largest settlement in OCR history.

Our enforcement program is busy. We expect to receive over 26,000 complaints this year. That is a lot. Most of our complaints are resolved with technical assistance, communicating with the covered entities, communicating with the complainants trying to address their concerns expeditiously to procure a positive result without having a lengthy investigation. Sometimes that is unsuccessful.

What are the cases that we try to identify? There are certain themes that we look for in the enforcement

program. Systemic noncompliance -- When we have a complaint or a breach report or we initiate a compliance review, we are looking at the overall health of the entity's HIPAA compliance program. Where we see multiple failures, then it is more likely to turn into an investigation that we would highlight in the enforcement program.

We also look for egregious violation of individuals' privacy rights. Sometimes it's not systemic noncompliance; it is just complete disregard of individuals' privacy rights and bad decision-making, and we try to highlight those for the industry so that people can learn from that and address their program.

In the entire history of the program we have had 65 settlements that included a corrective action plan and some monetary payment, as well as six civil money penalties. Two of those civil money penalties occurred this year. We had four civil money penalties for about 10 years and then we have seen two this year. So, whether that's a trend or is just case-specific, OCR always makes an attempt to resolve cases informally with covered entities but they do have the right, the option, the choice to enter into a settlement agreement with OCR or request a hearing or ultimately pay a civil money penalty.

Again, as I foreshadowed earlier, right of access is a common theme and it is an enforcement priority for this year. In February our Director, Roger Severino, announced that the right of access initiative would be an enforcement priority. Historically, our enforcement program just focused on breach, the failure to protect health information whether it be in the electronic or paper format. But breaches, the impermissible disclosures of individuals' information, that is important. We have not lessened our resolve to continue to do that work.

But the HIPAA privacy rules are bigger than that. A big chunk is the individual's rights, and that hasn't always been the focus. So we got together and talked about what are some of the priorities that we want to accomplish this year, what do we think is important, and elevating the right of access to an enforcement priority was key.

As I said, we gather a lot of complaints. One of the largest categories of complaints we get is the failure to ride the right of access. As I mentioned, we have done training, we have done technical assistance, we have done outreach, we have done guidance, we have issued regulations, and yet, 17 years after the original privacy rule it continues to be a major area of consternation.

We initiated investigations all across the country. I will be speaking about one of the investigations we completed in a few minutes, but those investigations are ongoing. The idea is that, through vigorous enforcement of this right, we hope to procure better results for individuals as well as covered entities, take a look at their processes, and help facilitate the right of access.

The common issues that we see within the enforcement program with respect to the right of access are untimely -- you have got 30 days. In many of the cases sometimes months go by, sometimes years, with no follow-up, no request for an extension, just it's not a priority. Or sometimes you will get that it's in archives and so we don't have to produce it. That exception doesn't exist; there is no such thing. So, untimeliness is huge.

Unreasonable fees, overcharging beyond the reasonable cost-based fee allowed by HIPAA. Form and format -- as we move to a digital age, people want their records in electronic format and covered entities oftentimes have the capability but choose or fail to produce it in the requested format.

Identity validation burdens. We have had instances where, in order for you to get your medical records you have to fill out a form and then get it

notarized and then come back, and then they will execute on it. That is unnecessary and unreasonable. There are ways to validate somebody's identity without making them chase down a notary.

This one is a common theme which I get -- somebody is changing providers and there's an outstanding medical bill. Send my medical records to Dr. Z across the street. The provider knows once I do that, you are never going to pay my medical bill, so I am not going to send your records to Dr. Z. I want you to pay my medical bill first.

I get it, but you can't lump them together. You can't do that. You have got to facilitate the right of access and you have got to achieve your payment in another way. It is not proper to hold the records hostage because of a nonpayment.

There are investigations going on all across the country and we expect to be announcing results. It will continue to be an enforcement priority because we think it's important. HIPAA provides individual rights as well as obligations to protect and secure data, and we want to make sure that the focus of the enforcement program is doing due service to both of those concepts.

This is a look back at the last 12 months of OCR enforcement activity. There are nine actions that were completed over the last 12 months, seven this year. Collections of over $13 million. As I noted last year, we collected over $28.6 million.

One of the things when you look at this chart, and it's something we are quite proud of, is we don't focus on one end of the industry. While we had a large settlement with a large covered entity last year, a multi-billion dollar entity, we don't only focus our enforcement on the big entities. The HIPAA rules apply to everybody including the smaller practices that haven't done anything to modernize and come into compliance with the HIPAA requirements, so you will see a great variation.

Over the last two years, our settlements have ranged from $10,000 to $16 million last year. We try to cover the entire industry and make everyone aware that you operate within a highly regulated industry and HIPAA very much places obligations on the entities to implement things, and you need to do that. What I think might be helpful is to highlight a couple of cases that illustrate the type of work that we see, as well as what the compliance concerns are. What are the patterns and trends that we see within the HIPAA enforcement program, where are

the areas that the covered entities are lagging behind in terms of the requirements?

One of the first ones there, Touchstone Medical Imaging from April 2019, this was a medical imaging services company that had been in business since 1991. We received information through a third-party source that patients' names, birth dates, addresses and social security information was exposed on the internet. It was on an unsecured server. Anybody could do a Google search and pull up individuals' protected health information.

In May of 2014, OCR and the FBI notified Touchstone, you have data on the internet and everybody can see it. The initial response was that the server may have been insecure but no protected health information was exposed. Ultimately, in October of 2014 Touchstone realized the significance of what two law enforcement agencies had told them and filed a breach report and identified over 300,000 people whose records had been exposed, and we began our investigation.

That is a good example of systemic noncompliance, and there was a failure to have access controls in place. Anyone could access a shared directory with patients' protected health information. There were no business-associate agreements in place. It was a deficient risk

analysis. Within the enforcement program, if you imagine a word cloud, risk analysis, the biggest words in the word cloud, continues to be a major stumbling block. We are not talking about little technical areas where reasonable minds can disagree. We are talking about fundamental aspects of the risk analysis that are not completed.

Start with this. You need to know where all the protected health information resides. For example, you may have an entity that has seven physical locations and they did a risk analysis, but it only covers two physical locations. It doesn’t take a long time to look at that and know you don’t have an enterprise-wide risk analysis that has identified all of the risks, threats, vulnerabilities, all of the ePHI when you don’t have all of your locations even analyzed in the risk analysis.

Response and reporting; When you receive notification from two law enforcement agencies that you have a problem, you have an obligation to look for known suspected security incidents. In this instance there was a significant lag in making a determination that the ePHI was indeed exposed and breach notification needed to occur.

The case settled for $3 million. It is a good example of systemic noncompliance that can occur in an

entity that felt like they had a secure program but upon further scrutiny there were major deficiencies.

With any settlement there is a corrective action plan, there's monitoring by OCR. In the monitoring we work very closely with the covered entities to help them during the monitoring period to implement items to come into compliance with the HIPAA rules as well as secure the individuals' data. There has never been an instance where we have gone after somebody in the enforcement program that wasn't monitored. We really do want to help the covered entities, and so all of the 65 actions that I identified that had corrective action plans, we have monitored them, worked very closely, provided technical assistance and hopefully implemented measures that would eliminate or greatly reduce the likelihood of that type of breach occurring again in the future.

Another case that I want to highlight is Bayfront Health. In September, $85,000. That was our first completed action in the right-of-access initiative. We announced in February we were going to make right of access an enforcement priority, and in September we had completed an investigation, entered into negotiations with the covered entity and ultimately were able to achieve a settlement and a corrective action plan.

The facts are fairly straightforward. A mother requested the fetal heart monitor records following the birth of her baby back in October of 2017. She was sent the lab and radiology reports but not the fetal heart monitor records. What was interesting in this case is there was actually a form with boxes that you could check what specific information you want and there was a specific box for fetal heart monitor records that was checked, so there couldn't be a lot of confusion about what exactly was the individual asking for. It was checked right on the box.

Complainant requested the records on multiple occasions, hired an attorney in December. Another request was made in January. Ultimately, the records were sent in August of 2018. The complainant had to wait over nine months to get her records, she had to hire an attorney and she had to file a complaint with OCR. We thought this was a great case to kick off the right-of-access initiative. It is not a complicated case. There is not a lot of discrepancy. The facts are not in dispute. It is an instance where someone should not have to wait nine months and pull all these levers in order to secure what they are entitled to by law as a matter of right.

What we hope, with the initiation of all these investigations and additional settlements or enforcement

actions to come is that covered entities will consider the next records access request that they receive could be the subject of an OCR investigation. It doesn't necessarily have to have something significant attached to it. It doesn't have to be an instance where an individual has cancer and wants their records because they want to send them to their oncologist. It could be an instance where somebody is changing dentists, moving from one state to another and just wants their dental records before they leave the state. The idea is it causes the covered entities to look at their internal processes and procedures and really put a concerted focus on this.

DR. PHILLIPS: Tim, would you mind saying just a little bit about the state health commission. How does the state health commission get pulled in?

MR. NOONAN: Sure. One of the cases, a recent civil money penalty, Texas Health and Human Services Commission. It started out against a slightly different entity, the Department of Aging and Disability Services in Texas, and there was a reorganization of the healthcare system in Texas and they created I believe it's two entities and one of them is the Texas Health and Human Services Commission, so that is ultimately who authorized

the payment of the civil money penalty but they technically were not in existence at the time of the breach.

This was a case where they had a software program that was used with the Community Living Assistance and Supportive Services Program. It was taken off a private secured server and placed on an unsecured public server, and it turns out it was there for years. Anybody could access it, there were no authentication requirements, there was no user name, or password ID. Anybody could access it.

There were 6,000 individuals affected, their names, addresses, social security numbers, Medicaid numbers, treatment, diagnosis information. And because of some issues with audit controls they don’t know how many people accessed the records, how many people saw it. The best estimate is the data was likely up there for eight years.

Potential violations included risk analysis. There was never a risk analysis performed before the breach occurred. The application storing the ePHI was not listed in an IT asset inventory, so it was completely untracked, had no access controls, no audit controls. So, anybody could access it and they don’t know who could access it, and we imposed a civil money penalty of $1.6 million.

Unsecured server is a growing theme -- I have a slide that touches on that briefly at the end -- in the enforcement program. With the movement of resources, you have an obligation to evaluate technical and non-technical changes into your information system, and when things get moved off of one server to another there can be dire, dire consequences and people need to pay attention. Taking something off a private server and putting it on a public unsecured server was a huge change in the environment and should have been identified in the risk analysis, had they done one. And they should have done an evaluation when they were undergoing those type of changes.

This is something we introduced last year in order to share with the industry. I like data. I believe in year-over-year data being the best way to convey trends and understand the changing landscape. You can see just in a five-year period of time the significant drop -- all of this data in the slides you are about to see are for breach reporting we receive for instances where over 500 or more individuals have been affected.

So you see the movement here from cases and reports received involving a physical theft of protected health information from 2014 to 2018, the physical break-ins, actual stealing of equipment that has PHI on it or the

raw data itself, boxes of medical records. It's a changing landscape. That is not where the activity is occurring.

Conversely, you can see for hacking, IT incidents almost a parallel rise. That is where the action is. You no longer have to break into a covered entity's facility to get the protected health information. You can do it from your basement. This is not involving incidents of unsecured servers; this is where somebody got in. This is the Ransomware type cases. This is when somebody does a phishing email. Somebody opens it up and it becomes an advanced persistent threat and starts installing malware in the information system. Password harvesters. Next thing you know they have administrative credentials and now they're moving all across the covered entity's information system being able to harvest the data.

Perhaps another way of looking at it -- the pie chart on the left is cumulative. In the entire history of OCR's enforcement program up to Halloween here, 28 percent of the breaches, 500 or more, involved hacking, IT intrusion. This year alone it's 61 percent. You can also see the drop in physical theft -- 31 percent historically including this year. This year only is 7 percent.

So we have gotten great feedback. We do a lot of outreach presentations, the HIP Division as well as the

regional offices, all across the country. We have included this information in our presentations. We want people to know, these are the threats you're facing. It is changing.

This is showing the breaches involving email accounts. As I mentioned, phishing is becoming an extremely popular common attack vector. Sometimes the weakest link in your security system is the individual. HHS does a fantastic job of doing the fake phishing emails. Every Christmas I get an email. You have an e-Christmas card. It's always the same reaction, oh, who sent me a Christmas card? That's nice. Then I have to pause for a second -- Nobody sent me a Christmas card. You click on it and, yes, this was an IT test. You passed the test, you identified it as a potential phishing email.

Those kind of rigorous programs -- because it's your finger, one click -- have tremendous consequences. We all know the pangs of regret when you send an email, you hit send, and then you're like, oh, maybe I shouldn't have sent that. That is the age we live in now, just a click. Clicking on something that you are not sure about can start a whole internal process that results in the exposure of millions of people's health information. So, running a rigorous workforce training, exposing them to the hazard

potential of phishing emails I think is key to understanding the environment.

We saw breaches by type previously. This is by location. Again, cumulative, entire history of the enforcement program on the left, and this year alone. You again see the email that jumps off the page. Network servers are becoming more commonplace. Laptops going down. Stolen laptops used to be a common occurrence. Why are there less stolen laptops? I think, I hope, it's because the covered entities have embraced encryption, and so if you lose a laptop it's encrypted and you are protected.

Some of the concerns and trends I will just highlight briefly. Ransomware is something we are seeing. They are targeting the healthcare industry because of the records. Phishing attacks, the unsecure servers. Multiple cases that were on that chart I showed you earlier. Cottage Health, Touchstone, Texas Health and Human Services Commission all involved unsecured servers. University of Rochester involved a lack of encryption.

We see weak authentication, single-factor authentication, and weak password rules. In many instances the password is Password. Not a great password.

Access controls, current and former workforce members. We have had cases where terminated employees

continued to have access to the health record system for months following their separation. You have got to have vigorous access controls in place; you have to have vigorous termination procedures in place. When somebody separates from an entity they cannot continue to have access; it is an impermissible disclosure.

MS. HINES: Tim, we would love to have time to ask you some questions. Is there any way you could wrap it up in the next couple of minutes?

MR. NOONAN: Yes. Lastly, audit. We have done two phases of audit. Audit gave us an opportunity to view the regulated industry from a different lens. Everything else was through compliance reviews, breaches, complaints where there was something that caused us to come in and take a look at the state of their HIPAA compliance. Audit gave us the opportunity. It was a randomized selection of entities, so we were curious are we going to see something different. Is this going to corroborate our findings within the enforcement program or is it going to show us a slightly different snapshot of what’s occurring in the industry as a whole? The short answer is it corroborates our enforcement program findings.

The key takeaways are entities that were audited have issues with risk analysis -- again, word cloud -- risk

management, addressing the deficiencies in the risk analysis, and right of access. The positive results that we noted in Audit was that the Notice of Privacy Practices were generally compliant, and the breach notification when a breach occurred, the entities were fairly responsive in doing it in a timely manner.

I agree. I think having an opportunity to have a little bit of a dialogue and questions would be fantastic.

DR. STEAD: Alix, Nick and Rich.

MS. GOSS: I wondered if you could give us a thumbnail sketch of your recent release of an updated -- I think you have been working potentially with NIST on the security risk assessment tools that have been released. Have you been involved in the release of the new guidance to help, or the tool, to help people with performing security risk assessments?

MR. NOONAN: Sure. We worked with ONC on our security risk assessment tool. It’s a great intro to developing a risk analysis. It is targeted ideally to smaller and medium-size entities. We have gone through several versions of it and did a recent patch, update, fix I believe last month. Again, the idea is there is a greater capacity now for entities to be able to enter in the program all the places that ePHI is stored and then come up

with a matrix for identifying the potential risk and threat to ePHI and then ultimately the impact that risk could have on the organization.

What I would stress, though, is that it is a tool, but it is not a guarantor of compliance. Merely filling it out doesn't mean you now have a compliant risk analysis and everything is sufficient. Like anything involved with a computer, it is dependent upon the data that's entered in it, so, if you don't identify all the places that ePHI is stored, it is not going to be something that will qualify as a compliant risk analysis.

What we have endeavored to do is provide more prompts, more identifiers to hopefully help folks identify all the potential places that the ePHI could be stored, but we can't contemplate or put together in a program every possible scenario, and particularly the large organizations where it would be much more of a challenge.

I would say we are very much interested in getting more information out to the entities. We do see it being used greater in our enforcement program when we ask for a risk analysis, which is normally the place we start with any investigation. Oftentimes we get, well, we used the security risk assessment tool. Well that's great. Then

you go through it and it will say something like not applicable. That is not so great.

It very much is dependent upon the user's data, but we have gotten excellent feedback on it. We maintain a portal where we can receive feedback and try and incorporate that in, so, over the years we have made it more comprehensive and more sophisticated to try and address the needs that we heard back from industry.

MR. COUSSOULE: Thanks for your time and information this morning. It is very helpful and enlightening. I am a little curious, you mentioned that surprise billing is a topic on the list. I know there are a number of potential pieces of legislation kind of running around now. Are you engaged in that process? I am not so much asking you to comment on any particular one of those, but what would be your main concerns with how it is being either presented or how it might come through from the legislative perspective?

MR. NOONAN: We have had some very thoughtful conversations with the folks on the Hill. Everybody has an interest and a different approach on it. I would say our concern is trying to figure out where do we place the responsibility for gathering all that information.

You're going in for a knee operation. You've got the surgeon, that's easy. But what about all the corollary services that are going to be involved? Who should have the task of identifying all of those folks that are going to be participating in it and figuring out who do they accept to participate with, what is the in-network cost, what is the potential out-of-network cost? Who gets that lucky job of gathering all of that and getting it to the consumer?

What is the appropriate timeframe? If I'm having surgery next week is that enough time to get that information? If I'm having surgery in two months, is that too far out that participation schedules could change? So-and-so is no longer performing radiology services with this hospital?

So it's understanding the placement of burden. It will be a challenge to gather that information, get it to the consumer, understand what's the appropriate time. That is why the listening sessions were great. It's the best way to do rulemaking, is getting input. That is why we did an RFI last year, it's why we held listening sessions, and we will proceed with some form of a proposed rule and really try to publicize it.

Rachel does a great job of making sure that we get that out to the industry. It is the comments that

really help us because we are not experts in all facets of healthcare, so it's understanding that problem.

Those are my biggest concerns -- who gets tasked with collecting all the information and what is the best timeframe so that it's meaningful for the consumer. If we do all this work and it ends up not being something that helps people, then it was a waste of our time.

MR. LANDEN: I would like to go back and ask about the health apps and the FAQs. I understand the patient has the right to dictate to a covered entity release my data to this app. My question is more about what has the experience been. Have the concerns about malicious app developers doing nefarious things with the hoodwinked consumer -- have they even materialized? Is that something that is being reported, and if so, who and the frequency?

MR. NOONAN: Great question. We don't have any jurisdiction over app developers that do not fit within the definition of a covered entity or more likely business associate. Our view, in terms of maliciousness or the frequency, is a bit constrained because it's not something we have jurisdiction over and it doesn't make up a large percentage of our complaints.

Anecdotally, what we get -- it's conferences and some complaints -- even if we don't have jurisdiction, what

is our level of awareness? I would say it is not necessarily maliciousness. It is the lack of clarity on what the app developer is going to do with the data once they have it. It hasn't been de-identified, it's protected health information, but it is not. Since it is not a covered entity, it is no longer protected.

The providers have been great. Their concern is does Mr. Smith really understand that you are sharing this. You don't know who this app developer is, you have never met him, you don't know if he's going to sell your data downstream. You have no idea what he is going to do with it. Are there some controls we can put into place so that there is an awareness? And we will publish it, put out guidance, et cetera.

But what controls can be put in place? And it's very challenging because we don't have jurisdiction over the party that is going to have that data. The area that we are concerned about is an area that, at present, OCR doesn't have jurisdiction over and so it's a bit of a challenge. But I think it's more along the lines of the uncertainty and lack of awareness of what can be done with the data.

MS. LOVE: This is Denise. Thank you for the presentation. You may have covered this and I missed it, or

maybe I should know this. The pricing of the information, is that a way to delay? I have heard stories where a patient will request their information from a given provider and the cost for producing that could be so high that it has the same effect as blocking it or delaying it. Is that a related issue? Is that still a relevant issue?

MR. NOONAN: Very much so. The two biggest concerns we see within the right of access complaints we get is untimeliness and fees. In some instances, it's both. The reason the records haven't been produced is because the covered entity has said we have your records and it's going to cost you $700.00. That goes way beyond the reasonable cost-based fee, the specifics that you are allowed to charge. So that is a concern.

We are taking steps to see what we can do in our modifications to the HIPAA rule to provide greater clarity on that specific issue. Right of access is of great concern to us and we are going to address it with all the tools that we have available.

Yes, the over-charging and the over-charging creating an impediment to the individual getting their records, creating the untimeliness aspect is a common theme that needs to be addressed.

MS. LOVE: And this isn't really anything you can fix and I don't know that anyone at this point knows how to, but in some discussions the government entities that govern data and maintain data and the responsible providers who do that are sometimes feeling at a disadvantage because you mentioned, you know, these big data venture companies and non-HIPAA companies are aggregating data at an astonishing rate, and they are not bound by the rules.

It almost creates, in my mind, and I am not there so I can be a little bolder maybe, that government or these folks are inept at good, timely information because we are constrained, but these guys out here doing what they are doing behind a black box but it sounds pretty cool are unfettered.

This is more of a perception that there are some sectors who are behind the curve and other sectors who are ahead of the curve, and in the public it's just a perception. I don't know how to fix it. It's just something that comes up on occasion, because those that play by the rules seem to be moving slower.

MR. NOONAN: That is a great concern. Big data is becoming a very popular topic, and it is something that OCR remains very interested in as well, so I share your concerns and thoughts.

DR. STEAD: I am going to let Deb ask the last question and then we need to switch.

MS. STRICKLAND: This might be slightly naïve because I know we have the same situation with the covered entities and not having the ability to control some of the entities that play in our ecosystem.

But, since you are trying to make some modifications to the law and what you cover, can you find a way to extend the coverage that you have so that you can cover these people who are saying they are going to be stewards of your health data, and if they are claiming to be stewards of your health data that they have to comply with the rules of privacy?

MR. NOONAN: Sure. Fantastic question. We are limited by the statutory authority that Congress gives us and so I think one of the issues is who is going to get that authority and then a suite of rules, perhaps HIPAA or something similar to HIPAA can be created. But right now, it is just outside of our purview. We don’t have the regulatory authority to be able to extend our jurisdiction. That is just one of the limitations that we face.

But there is a lot of activity, a lot of conversations, a lot of stories about that, and so I think

that is something that we're all going to see addressed at some point.

MS. STRICKLAND: Right. As you mentioned, we are far from where we were when the initial privacy stuff came about and there are lots of different applications and ways to use data in a very malicious way, so Congress and our laws have to move with the times and maybe move a little faster than the times to be ahead of the malicious acts and things that they can do to people.

MR. NOONAN: Yes. Keeping up with technology with regulations I think is challenging. We have seen the birth of whole new industries that just weren't contemplated back in 2000, 2002. We have got a significant piece of the piece, and we are doing everything we can within the jurisdictional authority we have.

I agree with your concerns. That is why I said buyer beware. When you give your stuff to a health app that has no connection to a covered entity, there are not a lot of protections in place if any.

MS. STRICKLAND: Thank you so much. Very informative.

DR. STEAD: Thank you. We really appreciate it.

Agenda Item: Redesign of NCHS's Health US Data Program

MS. HINES: we are going to make a gear shift over to Pop Health and I am delighted to have my colleague, Dr. Renee Gindi, here. She is with the National Center for Health Statistics, Chief of the Population Health Reporting and Dissemination Branch, which is in the Division of Analysis and Epidemiology. She leads the team that produces Health United States, and you all got the link to it and the materials in the pre-read.

Health US is the annual report on the nation's health submitted by NCHS to Congress and the President annually. Before working on Health US, she coordinated the questionnaire redesign for the National Health Interview Survey at NCHS. In 2017 she did a detail to ASPE, so she is good friends with our leaders, and she is here today to seek our guidance and counsel on the redesign. So, take it away, Renee.

DR. GINDI: Thank you all for having me here today. It is my pleasure to be here and I will say that this room is a far cry from the conference rooms in Hyattsville, so thank you for the D.C. experience. And, Rebecca, thank you very much for that introduction.

One thing you may have heard is that I helped to coordinate the questionnaire redesign for the National Health Interview Survey. One of the things I learned during that experience is that we could have sat a bunch of survey experts in a room deciding what we thought was most important to be collecting on that major federal health survey for the next 20 years. But rather than doing so, rather than thinking that we were the only experts whose opinions mattered, we spent a lot of time getting feedback from other federal agencies, from our sponsors and from the general public.

When I was given the opportunity to help redesign the Health United States publication, the flagship publication of NCHS, I knew that we really wanted to have that same experience, making sure that we were reaching out and getting feedback from all of our stakeholders from federal agencies, from policymakers, from academics and from the general public. And I am happy to be here with the committee today.

Just to give you a quick outline of what I will be talking about, I wanted to start off with a little bit of our joint history between Health US and the committee. For those of you who might not be avid Health US users I wanted to give you a quick overview of the report. And

throughout that, I will also be talking about some of the challenges that we're facing and then I will bring them more explicitly forward to talk about the challenges that we are facing as we go into our next phase of the report, and then I will hopefully have plenty of time for questions and your feedback on how you can help us improve Health US.

To give you a sense of the joint history, we actually, seems like, share a birthday. Although the committee was formed many years before the 1974 amendment to the Public Health Service Act, the committee's scope and size and role were expanded as part of the same amendment to the Public Health Service Act that created the Health United States report.

Kerr White, who was the NCVHS Chair between 1975 and 1979, said in some written remarks on the 25th anniversary of the committee -- he was talking about the Health United States report and really I think highlighting what our goals are. The first is to disseminate and educate policymakers and the public on the challenges facing the nation in terms of our health status, and also to improve the coordination between those agencies and organizations that provide and collect the data and those that analyze and disseminate it. I think that both of those goals are

still very much a part of what we are doing today and what we are looking to make sure we continue to emphasize.

NCVHS has historically served in a review capacity on the Health United States report, and I am very glad to bring back for your feedback the report as it goes into its next phases.

The Health US report, as Rebecca mentioned in the introduction, is a congressionally mandated report. We have been focusing on friends and the health of the Nation, and it has been published by NCHS since 1975. As part of our legislative mandate we cover four major subject areas: health status and determinants, healthcare utilization, healthcare resources and healthcare expenditures and payers.

I know some people really like to see the legislation and so I have it here just to emphasize that these are the four areas that we have been given, and to make sure that our team stays true to our original mission we do actually have copies of this around the office.

For those of you who are Health US users and may already be on our email list, you may already know that the Health US 2018 report was just released a couple of weeks ago. One thing you might recognize is the big comprehensive Health US report, this is the 2016 version. You may also

recognize the 2017 version which obviously looks a lot smaller. One of the directions that we're going in is printing less and less because, I don't know about you, but I don't tend to get my health information from large printed books anymore. We are doing a lot of conscious shifting of our materials to online access and the ability to access materials online.

There still will be a printed book for 2018. It will look a lot more like the 2017 version, much slimmer. There is no special feature this year for 2018. The special feature is a special analytic topic, mostly tax-based and a figures section. We opted not to do a special feature for this year as we spent time working on our redesign process.

Other parts that are not printed are the trend tables. Those are available completely online at this point. The Health US report still comes out and the main place to find it is now on the website. Like I said, there will be a print version by the end of the year.

We also have a number of other products, and I will be walking you through these today. One of them is the Spotlight Infographic. It does not come out on the same schedule as the main Health US report.

When you think of Health US, if you have used it in the past you may think of it as this large omnibus

publication, as a single entity, but really we are trying to think about Health US as a suite of products, and a suite of products that really tries to meet diverse audiences and meet the needs of diverse audiences. And we think about these audiences in a casual user, sophisticated user, in-depth user kind of way.

What I will do for the next few minutes is just go through part of our suite of products. I will use obesity and overweight as an example. I am not intending to present the data to you; that is not necessarily where I want to go today. I want to give you an overview and a flavor. You also might not be able to read all the text on the screen. Again, that is not the intent. It's the sense of what could different users see, and obviously if there is smaller text it's probably meant for somebody who is engaging with the text in a deeper way.

Just to give you a quick overview and then we will go into these examples, a casual user might be looking at our FastStats product, which is an NCHS product, not a Health US product, the highlights from the Health US report and the Spotlight Infographics. The sophisticated user might be wanting a little more information looking at our chart book with figures and analytic text, looking more at the patterns and analyses. And the in-depth user might want

to engage with the data directly or might already be analyzing NCHS microdata.

This is an example of an NCHS FastStats. In contrast to what Tim was talking about, they are very focused on making sure that information is closed off and only accessible to the right people. What I am going to be talking about a lot is the accessibility, how to make sure that information is not hidden away, and that appropriate health information is, in fact, available to all those who might need it.

FastStats is an NCHS product. It is, as you can see, very short, very much to the point. There is no methodology there, there are no pictures. It’s just the most recent number on overweight and obesity that exists. These are on html, so it should come up very quickly and easily through your browser or phone. It is Google-accessible or search engine-accessible.

One of the reasons that it ends up on my slide deck is that the Health US report actually feeds these factoids, these fast facts, on 33 of the FastStats pages, so it is definitely a source of ways to pull people into the Health US report and to make sure that information gets out.

One thing that I think is important to note and will come up again later, is that the FastStats pages on NCHS is the most popular NCHS product with over 350,000 page views per month. That is an important number for us to be thinking about.

This is an example from our Highlights. This is just pulling off of a pdf from the internal text in our report. The Highlights are, again, often just a quick, most recent number or perhaps a quick comparison from the first year in the period to the last year in the period and will provide a link over to the figure within the report. They are designed to be fairly easy to read, although I will say they are in pdf which is not accessible via search engines and is part of the main report, so, not necessarily pulled out in any particular way.

This is an example of our Spotlight Infographic. At first glance you might say, well, that’s just a regular figure that you would find in the rest of the report, but what’s more interesting is when you see what is put around it. This is something that’s aimed at that more casual user, not quite lay person yet, I would say. There are still a little too many numbers and comparisons perhaps, but I would say trying to get a little more visually interesting.

Our Spotlight Infographics are two-pagers, have a lot more graphics, deal with topics that are covered in Health US but potentially in a different way and are really aimed to be kind of crosscutting. This one was on adolescent health and this was one figure on obesity. Again, not a lot of methodology there but starting to at least point out what the data sources might be.

Now we are into what I think you might be used to as the Health US report. This is for a more sophisticated user. This has figures. There are plenty of footnotes underneath it in the main report. This is also buried in a very large pdf. There is analytic text that comes along with this, and this is where you might start to see for the first time more statistical explanation. This is the pattern that occurred, this is the inflection point, this is where we are seeing statistically significant decreases over time and increases over time, or comparisons between subgroups. This is the first part where we start to see a little bit more detail.

But again, this is our analysts highlighting -- in this case we have children and adolescents age 2 to 19, adults 20 and over, and so we are looking at it by broad age group, male/female, and we are looking at obesity. So

we haven’t looked at any of the other detailed subgroups or demographics that we have available to us.

But if you are looking for more detail and you’re a more in-depth user and you are interested and saying that’s great that you have given me obesity by men and women, but I want to know it by income group, or I would like to see it by race and Hispanic origin. Then this is a chance to go and look through what we call the Data Finder. And if you were a paper Health US user, you might have been familiar with going to the index to say I’m interested in obesity. Which tables contain information on obesity?

This is just an electronic version of that index. Again, we have the opportunity to go to the site, select a subject from a drop-down menu. Here I have selected obesity and overweight, and I am taken directly to a listing of the tables that are available to me.

Some of the tables are available in pdf. These are printable one-pagers. One of the issues with printable one-pagers is we have more information than can possibly fit on one sheet. Often, we will go down the rows to include additional information. Perhaps we have some tables that are maybe three printed pages long with another page of footnotes.

You will notice here that in the pdf you don't see things like standard errors, which would, of course, be necessary if you were doing your own statistical analyses. This is a pdf, so, therefore, it is not easy to graph or engage in your own data analysis. We only have in this case selected years.

Now, if you were looking at the Data Finder you could also pull up an Excel version of this table which then has all of those other pieces that I was talking about, has the standard errors, has additional years of data that might have been hidden in the pdf. And, if you are an Excel user, you know that you can either pull the others and the graphics yourself using that particular program or pull it into another software program that you prefer, such as some of the new data visualization platforms like Tableau or R or other html web-based materials.

Finally, I have the appendix which I think is kind of an unsung hero of Health United States because you might think, well, it's the appendix, it's just the end, it is not very important. But, if you are an in-depth user and you're engaging with these materials yourself, perhaps you want to work with the NCHS microdata and want to make sure that you are doing your analysis in a way that has been

vetted by the NCHS research team, then this is a place to go to say this is how we put together our obesity and overweight measure. Or, these are the ways that the question has changed over time, considerations you might have if you're doing your own trend analysis. Or you just need to know more about where to find additional materials. We also provide links to where we get our information as part of the appendix.

Hopefully you have been hearing throughout this initial part of the conversation about some of the challenges that we are currently facing. There are many more, but these are the ones that we will be talking about today. I think some of the current challenges that we are dealing with are understanding our audience's needs, reaching our target audience, and ensuring that we have easy-to-find information. We will go through these in a little bit more detail.

Of course, one of the things they tell you when you're working on a design or redesign of a product is that you need to understand what it is that your audience or your users need so that you are solving for their problem. Now, one thing that's wonderful about Health United States is that it is free to download for anyone on the Internet. And one thing that is awful about Health United States is

that it is free for anyone on the Internet to download. We have no registration, we have no way of truly knowing, other than metrics, how many downloads we have or how many page views we have. We don’t have a sense of whether we are reaching what we think of as our target audience.

Now, we have a congressional mandate, so we think that our target audience is policymakers. We know from some of the contacts that we get that our audience is also academics and some public health professionals. But one of the things that we are trying to do right now is understand who is our audience and what their needs are.

We have launched a web survey that goes along with our recent release from Health US 2018 and I believe to date we have gotten a whopping seven replies, so there is a possibility that we’re going to need some other alternative ways of getting that information.

Once we have a sense of who this audience is, we are really trying to work with stakeholders to understand their needs. That leads me to being in this room right now. We have been going around for about the past year, my team and I, talking with other federal agencies, with private institutions, with academics to understand what it is about Health US that they use, that they like, or, if they are not Health US users, what sources of information they

trust, and what are the features of these trusted sources of information that we could potentially also have.

We are also trying to adapt more quickly to changes in technology and subject matter importance. Health US can often feel like a very large boat that is very difficult to turn quickly, and in some ways we would like to be more responsive to whatever the most important topics are for our legislators so that they can make the best decisions based on good evidence.

Another one of our challenges is simply reaching our target audience. You heard me talk about page views and materials being buried in pdf instead of being in html. One thing I can actually start with is just by saying what are our metrics. In the past it would have been how many copies of Health US we were able to distribute. We have gone from a 13,000-copy print run to less than 1,000. Part of that is not actually problematic. Part of this is just a shift in the way that people obtain their information. In some ways, being able to put our materials online could potentially expand our reach quite a bit.

But again, thinking about what we can measure, when we looked at the page views and downloads for the first year of Health US 2017, this report, with the special feature on mortality, we had almost 65,000 home page views,

19,000 clicks on the pdf chart book and almost 240,000 visits to that Data Finder, that electronic index. I think some of these numbers sound pretty impressive, again remembering that the FastStats, the quick factoids at NCHS, get 350,000 views per month. So I think there is an audience out there for our data and for our report, but we are just not managing our technology correctly, we're not managing our access correctly. We want to be able to reach out to them as well.

Of course, once you actually make it here, can you find what you are looking for. We have been looking at the results of the last couple of years of the NCHS web survey, so, not a Health US-focused one but NCHS web-wide, and we read their comments. One web user's comment has stuck with me, that when they're searching there is so much information coming at them they can't find what they are looking for. So, how can we streamline what we are putting out to make it easier for people to find their own health statistics? And that actually leads us to a number of the discussion questions that I have here.

Again, I need to point out that currently, the way we put out this report is that it's all on pdf because we want to have an annual report of record that goes to Congress and that is the way that we currently put out an

annual report. But pdf versions of materials are not searchable by search engines, they are not accessible. So how do we think about -- other than putting out two completely different products, how do we think about making sure that those data are accessible to our users?

Our team sat down about a year and a half ago to think about our overarching goals for the redesign, and we came up with the goal that Health US will have an enhanced position as an authoritative source of analysis that describes the health of the nation and how it is changing over time. I think that authoritative piece is really important, and it’s one of the things that we are very grateful to be a part of, NCHS, because that is, of course, a respected name in the statistical community and should give people confidence that the data they are getting are official statistics and are used appropriately.

For the past year we have also been engaging in a number of redesign projects and we have, we think, a good way to get to this goal. Just to give you a quick overview of how we’re conceptualizing our redesign, our primary activity right now is input and gathering data to help make the best decisions possible. We are spending a lot of time right now in our process as we try to think about whether our product grows in terms of number of subjects.

Right now we are covering about 65 different health topics as part of the report, so, do we want to grow that breadth. Do we want to go more in-depth analytically? Regardless of which way we want to grow, we need to do what we are doing right now more efficiently so that we have time to do these additional pieces.

Also, once we have both our input and process in line we're going to be spending more time on synthesizing that information and figuring out how our content needs to change to meet the needs of our audience.

And finally, dissemination. I think we used to think that our job ended once the report was out, and I think what we're learning is that that is not really the case anymore. If we want to be able to have that reach and have that visibility, we have more work to do on disseminating the report.

We are doing a number of things right now as part of our input strategies -- the stakeholder interviews, the web user survey, for better or for worse, literature reviews to see how the academic world is citing our work, and quite a bit of web analytics to figure out how people are getting to our site, and market analysis to understand a sense of what's happening in other reports that are like us, what other features do they have to meet some of the

needs that we have already identified, and then trying to understand more about the audience that we know about.

That is the bulk of my presentation. Now I was hoping that we could turn to the kinds of questions that I brought with me today. I know that one of the things that, given our redesign timeline I didn't talk about, we are really looking to wrap up the main input portion of our work pretty much by the end of this calendar year or January of 2020, and then we are going to be moving into this content synthesis phase. So I think that in terms of timing, we can hopefully have a good discussion here, and I would say that you should feel free to let me know if you have additional feedback on your own.

In terms of what I am here to ask of the committee, I was here to have these initial discussions, give you a sense of where we are coming from, and then what I would hope is perhaps at a future meeting to be able to bring some of that synthesized content to really get feedback on whether this new product might meet some of the needs of the committee or others of the interests that we represent.

Before we move on to discussion questions I should actually ask if there are any questions from people

in the room or on the phone about the materials I have discussed.

MS. HINES: Anyone on the phone? There are no tent cards up in the room.

DR. PHILLIPS: Renee, thank you so much. It's really good to see where you are going now that you have had a chance to redesign. This is really important. I will tell you frankly, my 11-year old daughter loves the wheel, the mortality wheel, that you all put out --

(Laughter)

One of my questions is our Population Health Subcommittee and subsequently NCVHS, developed a measurement framework for community health and wellbeing that IHI and then 100 Million Healthier Lives took on as Wellbeing in the Nation. Are you working with them in any formal way?

I bring it up because they are working with NCHS and CDC for Healthy People 2030, they are working with other federal health agencies, and I see a way that you all could either align some of the measures for presentation and become a source or you could be a source for people wanting to produce those measures. I just think there's an alignment there that would be interesting to explore.

DR. GINDI: I think that is a really great point especially on the content side when we're thinking about what measures we are missing. We have quite a lot here, but we certainly get questions on where is -- insert statistics here -- and I think that aligning those frameworks, especially for people who have already done the work and are thinking of what the important measures are for the next decade, so I think that making sure that we are aligned does seem like a good idea. Thanks.

DR. STEAD: Thank you. A little bit along the lines that Bob mentioned, what we did in the work on the measurement framework was to step back and say that we needed a non-health centric dashboard of the key things that affect health. Obviously, that includes the parts that are health-centric, but it shifts the balance.

We thought it was very important to have every cabinet level secretary see things that are important to them at the top level of this dashboard so that they could then see opportunities to work out what they are trying to do in conjunction with what other departments and sectors are trying to do to collectively shift determinants. So these comments may relate more to the determinant sector of your report than the other pieces.

Just speaking from my local perch in Nashville, Tennessee, we have these marked discrepancies across co-located zip codes. Senator Bill Frist, since he has been back in Tennessee, with the help of the measurement framework and what IHI has done but also with others, has really built a regional data resource. If we could figure out ways to hook these things together in some way it would be extraordinarily helpful.

Action increasingly is local. We need to have the national landscape and the local variation -- knowing where Tennessee fits actually isn't very useful. We are just so disparate. So I don't know if there is some way, as one looks at the online presence, to figure out how to establish even loose links to related sources in the IHI work, in the Kaiser Family Foundation work world and RWJ. If there was some way to let us hook some of these things together it would help us get traction.

DR. GINDI: I found that when I talk to media folks as a stakeholder group as well, that is quite often the number one thing that they are asking for: what could we do better? You could give us more geographic granularity. That is not necessarily something that our report can give, but I think exploring the idea of links

and loose links to where those data can be found makes a lot of sense.

DR. STEAD: And so that your report becomes the overarching context, so it’s not an either/or, or making you do the stuff they are trying to do. It’s basically look at it like a global kaleidoscope.

DR. PHILLIPS: It could become a gateway to other resources where you can take a deeper dive. Exactly.

DR. GINDI: One of the ways that we were trying to take some of those steps back, rather than saying are you a Health US user and what do you like about it and what do you not like about it, we wanted to try to say, well, more globally, when you’re thinking about the kinds of questions that require you to look for health statistics, we wanted to know, even just thinking about that, where you usually go to start your search.

And I am actually interested in this particular audience. Where do you go to start your searches when you have questions that require health statistics? Maybe you’re a book person, in which case that is good to know as well.

DR. STEAD: I am just trying to think how to say anything that would be useful. I have learned I have to go to multiple places for any search, so maybe that’s the sound bite.

Another thing I would just suggest you skim is the National Academies' report that was released in June on guiding a national cancer control strategy. That would be worth a read offline from your pickup.

MR. LANDEN: I am not a data professional nor a statistician but I have worked with data before, so I am kind of in between. When I start a data search, I will go through a search engine -- Google or what have you -- look at the returns, and I will go then to any returns I see that come from NCHS. Secondarily, if I see non-NCHS sources, depending on whether I have name recognition or not, I will go to them next and just keep going until I find what I want.

DR. GINDI: Thank you. That is helpful. Sometimes, if we have name recognition that is great, but we do have to show up on the top searches.

MS. HINES: On the phone, anyone want to weigh in on the discussion around how you search for health data?

DR. CORNELIUS: I think the issue for me is I separate the difference between data and reports. For the reports, I may go to NCHS or AHRQ or SAMHSA. I will go to the federal sites and then go to the state sites for pdf reports and, obviously, to think tanks for reports, like the Urban Institute.

The data is a different issue because it really gets into where secondary data -- some of it might be things that NCHS talks about that are at the Research Data Center or AHRQ or so on and so forth, University of Michigan. And that is why I have to really separate what I need now versus what I would need to access --

MS. LOVE: I think it depends on what is the question. If it's price transparency, I'll go to some of the states' health cost sites or HCCI data. If it's health statistics I will go to NCHS, CDC, depending on the topic, and then down from there. But the biggest request that I get is for granular data, and there's a real push for geospatial sub-county levels which a lot of our datasets have trouble supporting.

MS. HINES: Frank or Jacki?

MR. LANDEN: Have you thought about or gotten any feedback about a virtual assistant approach, kind of an NCHS Siri? That is not a technique that I use but I know of a lot of people that now live and breathe with that type of technology.

DR. GINDI: That is a good question. We have not necessarily been exploring that directly through Health US, but there is some work at NCHS going on right now to help provide data and information, to also encourage survey

response, and so there is some interesting motion in that direction.

But again, it is a question of who is the user for the product that we are putting out? We don't want to try to do everything and then do nothing well. We want to try to meet those audience needs.

One of the places that we are going that I think is a little bit more lay person, in that same sort of vein, is we are trying to do a little bit more on social media and putting out visuals that are more social media-appropriate. You saw the figures that we had. Those are not really going to go viral on Twitter.

But taking some of those same approaches that we were using for the Spotlight Infographic, more big arrows, big words, webolt type people to try to get some statistics across. Those have been doing a little bit better. We have been experimenting with that.

One of the comments that we got at an academic stakeholder group, faculty said that sometimes when they are getting ready for a lecture and they just want a quick visual for a statistic that they're showing that sets the frame for the rest of their conversation, they go to Instagram. Apparently, WHO has a good health statistics account where they are able to just go in, pick up a quick

visual on worldwide maternal mortality, and then go from there. So that is another place that we're looking at expanding into. Again, not quite lay person, but meeting some of those academic needs that have been identified.

MS. HINES: Anyone else?

DR. PHILLIPS: I think, to echo Denise's comment about granularity, that really is increasingly the name of the game. I think this platform is incredibly important for its consistency and the trend capacity to look at data over time, and I do come to it regularly for the high-level look.

We had an event at the British Embassy this last June and Amy Kind from Wisconsin came in and was using the area deprivation index and their neighborhood atlas, and there was almost a gasp in the room when she went from state-level metrics of social determinants down to Milwaukee. The whole area of Milwaukee looked one color, but when you went to that level of granularity of Census tracts it changed in a remarkable way that really helped you understand where problems were versus non problems.

That level of granularity I think is what people are really looking for to know where do we target resources or other things. As I said earlier, I think you could be a gateway for people looking for that granularity, to become

a place where people come first and then go subsequently to find more.

MS. LOVE: Bob, I would echo that. We look at state-to-state variation or regional variation, but you start getting into those variations with a smaller area and it really opens eyes and can point to the hotspots. The hardest part is getting access to that level of data, or if we can get access to that level of data, how we you share it, because so much of that data that we can get is prohibited from being disclosed. And that gets into we need some more work I think on clever ways to do that.

I don't know much about it, but I have heard a lot of promise about maybe creating synthetic datasets that mimic the real thing but we aren't breaking laws by displaying it. But there is a lot of work I think that needs to be done in that regard.

MS. HINES: We are just about out of time. Renee, I think what we will do is we'll let the members chew on this some more and we will get you any additional feedback and then we will stay in close touch. When you are ready to come back, maybe we will have a little more time on the agenda if you want to drill down more on your progress as you move forward on this. And thank you for the context. I had missed the Kerr White quote from 1974, whenever that

was. That was quite amazing that you had all the context for this.

DR. GINDI: It's amazing what you can find on the internet these days.

MS. HINES: All right. We are going to take a 15-minute break and when we come back Bob is going to lead us off with our next presenter, Margo Schwab, on the federal data strategy and actually how it relates to some of the questions that we were just really getting into around helping users get access to not only sub-state and sub-country data but really at the local level, so we are going to continue this discussion.

Bob, did you want to add anything?

DR. PHILLIPS: Committee meeting updates were on there. Do you want me to do a really brief update?

MS. HINES: Yes, we will lead off with that after the break. I missed that, thanks.

(Break)

DR. STEAD: Okay, colleagues, we will reconvene. We want to take a few minutes for brief committee updates after one quick announcement.

(Lunch arrangements discussion)

Committee Member Updates

DR. STEAD: I will start the committee update process. Rich, would you like to say a little bit?

MR. LANDEN: On August 27th, on behalf of the committee, I addressed a group called NPAG, National Plan Automation Group. This is I think the fourth year that I have addressed that group. The group is comprised of people who are mostly at the middle management level and they work for the various Blue Cross/Blue Shield plans across the country and their area of focus is the connectivity between the Blue plan and the provider. So, for the Standards Subcommittee it's a group that is fairly in the bull's-eye of the piece of the industry that the subcommittee deals with.

In previous years I had provided them information on some of the things that we were working on, mostly around the Predictability Roadmap and the various aspects over the years. This year, there wasn't as much of an opportunity for me to give them information which they would digest and feed back to us, not usually directly but mostly going either through their parent Blue Cross/Blue Shield plan or more commonly through the Blue Cross/Blue Shield Association.

I kind of closed the loop on them, gave them the follow-up on the Predictability Roadmap. I had the pleasure

of watching some eyes glaze over and some jaws drop in horror as I approached the subject of ICD-11.

(Laughter)

And I went over with them the last 12 months of the NCVHS work products. I spent some time on the collaboration with ONC, the prior auth, the attachments, the conversions of administrative and clinical data. Interestingly enough, separately on their agenda and separate from my presentation they had agenda items also dealing with attachments with DaVinci, with Fire, and a lot of the connectivity HIE issues.

I also described to them the work we have been doing on privacy and Beyond HIPAA and where we were going with that, so that was my 45 minutes. Questions?

DR. STEAD: Thank you. Bob, I believe you had something to share.

DR. PHILLIPS: Just a brief walk down memory lane. You remember last summer in June the Wellbeing in the Nation Measurement Framework was formally announced. This is a 100 Million Healthier Lives collaboration, a public-private partnership with us. If you recall, it also includes a note from Bruce Cohen as Co-Chair of the Subcommittee on Population Health and it includes a letter from Bill thanking them for that collaboration.

That measurement framework, as you may also recall, is built on our framework with the addition of wellbeing and equity measures. In this last month, I am happy to announce, it has become a formal network. So, the WIN network has several formal partnerships now. There are several WIN partners that are public entities, policy entities, that are really taking up this measure set and using all or some of it in some way.

It is being pulled into a formal partnership with Healthy People 2030, so, CDC and NCHS. There's another major federal partnership that will be announced soon that is going to be using this on the HHS side.

Bruce Cohen and I have joined the WIN leadership in producing a full paper about not just the measures but the process that we went through, and Millbank Quarterly has invited us to submit that. The former Assistant Secretary for Health and National Coordinator for ONC, Dr. Karen DeSalvo, has co-authored a paper with Somava Stout about the process and the creation of a public-private partnership and the process of bringing stakeholders in to really take something that NCVHS could create and turn into something even more robust and widely used.

As Somava points out in conversations we have had, there is a lot of passive uptake of this, so, people

who aren't entering into a formal partnership can find it and find it valuable enough to just start using it. And that is a real sign of success.

I just want to emphasize that the NCVHS measurement frame for community health and wellbeing has really been taken far beyond anything we anticipated and frankly demonstrates a fairly strong federal agency appetite for the work of the committee, and I think there is more to be done.

I am very grateful to Dr. Somava Stout and 100 Million Healthier Lives for bringing in so many stakeholders and for producing an actionable array of data elements for community wellbeing and assessment, and just thank you all for your ongoing faith in that process.

DR. STEAD: Thank you very much. As I mentioned earlier in my comments, the framework and the supportive relationships we put into place through that work were very helpful to Senator Frist and the leadership group in Nashville when they decided to create a multi-county local resource that is guiding the collective action there. Thank you.

One thing from myself, Linda Kloss and I presented the Beyond HIPAA approach to health information privacy at the recent NIST OCR conference. Rachel helped

create that opportunity for us, and we have had a number of follow-up connections from that. One that is actually flowing into this meeting was the public policy team, IT-AMIA, connecting it with this, and their work around health apps, some of which was reflected in the Agenda Book, is aligned with what we were discussing in Beyond HIPAA. And since they are set up to lobby, they made the connection of the report into the Senate health committee, so I think the spread is continuing.

Any other updates? Nick.

MR. COUSSOULE: I was asked to give a discussion and presentation to the AHIP, the Health IT and Interoperability Workgroup on September 13th and really walk through the Beyond HIPAA path and report. You are familiar with AHIP, Association of Health Insurance Plans, so there were a lot of health plan policy folks and I just walked them through a lot of the work that has happened in the Beyond HIPAA realm and then reviewed some of the recommendations that came out of the report.

In addition, I am actually speaking at a forum in December on the consumer experience in digital health. It is not in relation to me being specifically a member of NCVHS but it’s covering a lot of the same topics. It is a panel called Health Data Transparency in the Public Domain,

and Devon McGraw is one of the panelists as well. I won't be there specifically as a member of NCVHS, but it will be some of the same things that we talk about here.

DR. STEAD: Outstanding. Any updates from the members on the phone?

DR. PASQUALE: I am fine. I have time on the agenda later today so I will refrain from updating here.

DR. STEAD: Then we will turn the meeting to Bob.

MS. HINES: For the members of the public and members on the phone, there is solid security entering this federal building. We are very safe here, and our next speaker is going through that right now and will be here momentarily, so we will just pause for a couple minutes.

(Pause)

MS. HINES: We are resuming to the agenda item for this morning, the update on the Federal Data Strategy, and Bob Phillips, the Co-Chair of the Subcommittee on Population Health, will start us off. Thank you, Bob.

Agenda Item: Updates from the Federal Data Strategy

DR. PHILLIPS: I am pleased to have with us today Dr. Margo Schwab from the Office of Management and Budget, but before I introduce her I want to recap a little bit why we are honored to have her with us.

A moment ago, I gave an update from the Population Health Subcommittee, Margo, about our measurement framework for community health and wellbeing that then was taken on by IHI's 100 Million Healthier Lives and developed into the Wellbeing in the Nation first measure set and then a network. So it's a product of small area measurement of wellbeing and health that now has been taken through a whole stakeholder process and developed into a measure set that now is being endorsed by lots of organizations and used by lots of organizations as a platform for assessing health and wellbeing in communities.

As this was launching, as that public-private partnership was developing, almost a year ago we held a hearing as the committee with several stakeholders about the loss of some key federal data tools that many communities were relying on for assessing the health status of their population. So, kind of at the same time the framework was being launched, the process by which you could get data to populate it was going away. And we got a lot of letters in addition to those who came to testify about the same issues.

So we started as a committee tracking the foundations for the Evidence-Based Policymaking Act of 2018 as it was being developed into regulation and then the

related Federal Data Strategy. At our last meeting, I presented on the draft Federal Data Strategy action plan and the committee actually then submitted formal comments in July that made a key statement. We weren't making recommendations, but it was feedback into that Draft Strategy Plan.

We said that the committee observes that if data or analytic products at the community level -- that is to say, sub-county -- were produced out of the federal statistical research data centers and made public, it would better support local assessment and evidence-based policy-making. The development of additional action steps to support creation of public outputs from those FSRDC data holdings would further this goal.

In recognizing that OMB has a key leadership role for the Federal Data Strategy along with the Departments of Commerce, the Small Business Administration and the Office of Science and Technology Policy, we are really delighted that you would come and talk with us about what may come next. We really appreciate the call that you had with Rick and I about laying the groundwork for some of what we hope we might get addressed today, but particularly how the Federal Data Strategy could contribute to community health.

For the rest of the committee and for the folks on the phone, I want to introduce Dr. Schwab. She is the Science Advisory and Policy Analyst at the Office of Information and Regulatory Affairs in the Office of Management and Budget. Her principal roles are to advocate for science-based regulations and to promote statistical and scientific rigor in the information produced and disseminated by the federal government.

She provides government-wide leadership in the development and implementation of policies associated with information quality, peer review and scientific integrity. Her work includes ensuring that the principles, integrity, utility, quality, privacy and security are fully honored as the government makes its information ever more transparent and accessible to the public.

Before coming to OMB, Dr. Schwab was on the faculty of the Department of Epidemiology at Johns Hopkins School of Public Health, and was the Assistant Director of the Risk Sciences and Public Policy Institute where her teaching focused on the use of science in public policy.

Earlier yet in her career she conducted environmental epidemiology research at the Harvard School of Public Health and Mantech Environment, which contracted with the U.S. Environmental Protection Agency, and she also

worked at the Council for Scientific and Industrial Research in South Africa and the University of Colorado. She received her PhD in geography from Clark University.

We are so glad you are with us today, Dr. Schwab.

DR. SCHWAB: Thank you for that introduction. I want to make a comment on your comments. I found that the comments that you all submitted on the Federal Data Strategy were excellent. There were a lot of folks that commented that haven't really thought about these ideas, and, as you point out, the things that you have been thinking about, the Evidence-Based Policy Act and the Federal Data Strategy actually fit very well together. It's not as if it was like, okay, how can we shoehorn this in. It actually fits within the context of what we are trying to do, and so I wanted to start with that.

MS. BERNSTEIN: Margo, could I interrupt? Would you introduce your colleague briefly?

DR. SCHWAB: This is Quinn Hirsch. She is also at the Office of Information and Regulatory Affairs. She is our public health specialist and she is the desk officer for incoming requests for collecting new data in terms of CDC, HRSA and NIH, and she also does a lot with Medicare and their work and regulations as well. We thought it was a good fit to have us both here because she is actually --

where some of the most valuable data lie is actually through the CMS collection system where they have data on pretty much everybody 65 and over.

Those of you are probably aware in this group, during the last 10 years, the Center for Medicare and Medicaid Services has turned its data from a billing operation into a more data access operation, and people have been using those data in a lot of really interesting ways so that it is no longer, oh, why would CMS be at the table. They are now thought of in terms of public health data availability. So we want you to think of us as a team because we work on different aspects of things.

We want to just take a step back. In terms of feedback that we have had on the Federal Data Strategy and the year one action plan, in Phase 1 we had 218 submissions; Phase 2 was 198 submissions, and Phase 3 was 185 submissions, so we have gotten a lot of feedback. Currently, what's happening is they are working on the updated action plan. We hope to have that out by the end of the year, hopefully much sooner but clearance processes being what they are, especially during budget season at OMB, sometimes it takes longer to move things through than you might like. Hopefully we are going to have something for you fairly soon.

But I want to talk just a little bit, before we go back to your comments, about some of the areas that we have been thinking about in the federal government where we feel that we need to focus. If you think about it from OMB's perspective, we are thinking about how do we get all the agencies to actually buy into this idea. I have been at OMB 17 years now, and that is really the biggest challenge. You can come up with as many frameworks as you want, but getting folks to follow through -- and I want to just talk a little bit about it at the big picture level but then draw it through the WIN network, because I think, again, it is pivotal.

One of the things that we are working toward is thinking about how do we -- this is a federal data strategy, and the idea is that we would have consistent roles and responsibilities in data management across agencies; that we would have consistent governance processes and consistencies in how we are addressing policies. Harmonization, though, is great in theory, but in practice when you are working across agencies with different statutory mandates and different cultures internally, the question is how do we establish data as a priority in the organization.

And I brought up CMS for a reason, because they actually did make a major change in how they value the data that they were collecting as part of their administrative processes, and we have ways now that that data is much more available to the public instead of just start with a university getting all the tapes and that's that, and nobody else seeing them. So it is possible for an agency to evolve into that.

What we are grappling with right now is we put out this guidance and then we take a specific agency -- and since we are at HHS we will talk about that for a second -- that we have different agencies within that have their own cultures. CMS is one agency within HHS. How do we work with HHS and how does HHS start to think about what kinds of processes are going to help them start thinking like, instead of here is our policy and we need some data to support it, to, take this bigger step back where we are saying we're looking at the data and trying to figure out from the data what it is we should be doing. That is something that, again, small parts of HHS do have a lot of experience in. For instance, National Center for Health Statistics is all about producing data so that people can look at the data and say, okay, what do I do, as opposed to starting with the policy.

But HHS, Department of Interior, Department of Transportation have so many different components, and we are trying to work at the department level and that's really difficult. And I think one of the advantages that you all have is that you could be targeting specific sub-agencies. Instead of targeting HHS with, okay, HHS, this is what we think you should be doing, I think you have the advantage of saying, okay, for certain indicators that you have identified -- and you have the wellbeing indicators and the environment indicators.

And one of the things I wanted to see if maybe we could get some conversation around is are there agencies that are specific -- instead of saying to HHS it would be great if you collected more small-area data, the question is can you now take this to the next level and say, okay, the areas where we are missing the small-area analysis are in these key areas, and sort of prioritize what it is and which agency you want to have a conversation with, instead of HHS as whole, if it's an FDA type of data or CDC type of data, and then working specifically in terms of the data needed for those measures.

Because I think one of the things that we are finding is that -- and OMB has a long history in this area of saying this is what we should be doing; work at the

department level. But that rarely helps get at what you guys have raised which is the lack of data. And I like how on your website you can go into an indicator and see the national, see what we have for states, and then click on a state and see whether or not we have that information.

It seems like, if I'm reading your comments well, and after looking at your data site and all, like the next step might be to be much more specific, because what I don't want to happen is to see your ideas here and people say yes, they dovetail perfectly and that's great, but I think that folks that need a little bit more detail. I would say like if you're going to take this to the next level in the context of the federal data action, and even though the action plan is going to evolve and they are still working on it back and forth across components of OMB, so hopefully we will have something soon.

But the point is, even if what's highlighted here, which are really actions for the agency and the department to provide a framework, one of the things that I think might be helpful is focusing on a specific agency or two agencies and really trying to figure out what kinds of information they might have and that you guys could work with.

One of the things I think we're seeing is inconsistencies across agencies, across departments, and not necessarily -- Many of the folks who are the receivers of the data strategy often don't have the workforce capacity or the expertise to navigate these kind of data integration requirements. And so thinking in terms of how you could move something forward, I'm wondering if you would be -- I mean, I can talk forever about all the problems that are up high, but really that is not going to get you what you need.

And so I was hoping that maybe we could talk a little bit here about the kinds of data -- like, if you were going to prioritize the kinds of data and we could do some brainstorming about which agencies within the department and which kinds of data, you might be able to make a much more specific ask to help you move forward on this effort.

Like I said, it dovetails at the top level, but I want to make sure that you are actually getting what you need.

DR. PHILLIPS: Margo, let's say we were to create a matrix -- well, we have a matrix already that says here's the high-level thing we want to measure, here are the metrics, the actual measures that have data tied to them.

Next would be to say this is the department or the agency that manages those data currently. So, if we develop that matrix without hitting each one individually, is there a way to come through the Federal Data Strategy or the data council to say that this is the collection of data that we would like to be able to access? I will come back to "we" in a minute. Is there a way to bring these together or to tap into these in an FSRDC, for example?

The next step is, if the answer is yes to that, and I think it could be if the data are available, it's who. Who can go into the FSRDC and pull those out in a way that other people can access it, is kind of the next question because it is difficult to get into one of them and be able to produce a data tool or a data resource.

DR. SCHWAB: Yes. Taking the first question, I think one of the things that would be helpful -- and I know that all of our children are special and we don't like to prioritize, but I think the only way we are going to get the data strategy's attention is to say here are a set of related indicators that would draw on the same sets of here's three datasets that we need access to, or the three types of data -- even if you don't know what those datasets are, which in many cases even a lot of the folks that we're

working with in the agencies don't have a clear idea of what all the options are.

So it's narrowing this down a little bit to say, okay, we are going to do like a case study -- and I don't know whether you have spent much time on the Federal Data Strategy site but they do have some use cases. I wanted to encourage you to think about taking just one piece as a use case. I think wellbeing might be one of the harder ones, so we could go more with one of the health ones that we are pretty sure we have more data on than are currently publicly available, and really flesh out in a way that's -- okay, for these five indicators, they all need data about long-term health of the elderly, or whatever. And then, what agencies are those most likely to have data like that.

Then start out with something where you might just have a meeting with one of them and lay out -- because I think what has been really difficult is to not -- we ran these trainings for the chief data officers and chief statistical officers and the chief evaluation officers, and for them it was like drinking from a fire hose because, even for the agencies that had chief data officers in the past, they had a certain job description, for want of a better word, and they were doing something. But all of a sudden you're saying now, under the Evidence Act, here is

what your responsibilities are, and they're like, whoa, whoa, that's a lot, and we don't know how to get our hands around it.

So, what I'm concerned about is, by the time we are able to get these people engaged, it could be way too long before -- it is not going to be helpful for you. But I think if we can break this into bite-sized chunks and then feed them to, instead of the HHS data officer, we feed them to the CMS data officer or to the FDA data officer. And you actually work with them, saying here is what we are trying to achieve and here are the kinds of data. And then they can be your partner in trying to ferret out like, okay, what kinds of data might we have that actually address these three building blocks for the indicator.

I am just trying to be realistic about how to help you move forward on this, because right now the focus in OMB, like I said, is really at the department level, and it's really about how do we address these inconsistencies and how do we try and get complete data inventories, and how do we get agencies to go through the process that CMS went through where the policymakers are seeing that there is real value in starting to mine the administrative data. But if there is not value to the specific policymaker in

terms of understanding what he or she could do with that data, then it's just another OMB requirement.

And so, in terms of making this discussion a little bit more focused -- Like I said, I think you are miles ahead of where other organizations are in terms of thinking about the big picture. But in order to harness the energy behind here I would really think about focused use cases and then bringing those forward, and not necessarily through HHS but, like I say, going directly to the agency and getting a partner who's going to see the immediate value for them, rather than trying to convince HHS as a whole that this is a priority when that person has all those other agencies trying to vie for attention.

MS. HINES: Margo, your comment is interesting because there really isn't a home, as far as I know, legislatively anywhere in HHS where sub-county level data responsibility lives. And so, when HRSA in the late 1990s and 2000 launched the community health status indicators, it was because the Administrator understood that his audience, oftentimes nonprofit, underfunded organizations applying for grants, couldn't hire an epidemiologist to say why they needed the grant.

So, what has happened in the last 20 years is that the need for these data with community health needs

assessments has just blossomed, as you know. And under Bob and our previous Co-Chair, Bruce Cohen, in essence they have done what you have already asked us to do. They went to all the different secretariats -- we had people from the Environmental Protection Agency, we had HHS, we actually had people from Transportation and Census. They know who some of their power users are or would be if the data were available -- and we basically developed a framework of here are the measures for which we need data.

And so, what Bob was saying is to some degree we were able to mine those data from various federal sources, and for whatever reason, mostly budgetary, a lot of that capacity has diminished or even disappeared. So the question is now that the needs assessment has been done, the use cases have been done, we figured out across these domains these determinants of health and wellbeing, how can we leverage the Federal Data Strategy which basically is saying let’s make data available? Well, here is the population of the United States and their leaders, their local community and public health leaders saying we need these data.

As Bill was talking about earlier in Nashville, you have zip codes co-located. One is in the bright red and one is light purple because just two neighborhoods next

door have life expectancy discrepancies of 20 years. And so we need data to help figure out why.

The question is how do we penetrate the resources that are available even though nowhere in the department is there a mandate, if you will, and yet, there is this incredible need that has been identified? And this committee in its capacity to engage data stakeholders and basically since 2012 has been engaging over the years until it culminated in this framework which was then turned over to IHI's 100 Million Healthier Lives, I feel like we have hit this wonderful precipice where it's like, okay, can we make this come alive, can we connect it with federal data sources and others. And I don't know that going agency-by-agency is going to do it.

DR. SCHWAB: Well, because the Federal Data Strategy and the Evidence-based Policymaking Act are really about using available data, in many cases, that is why I think that you would probably be going to different people than you went to before. So, instead of what kind of indicator would be useful, you are going to somebody who probably doesn't really look so much at what your public health goal is but somebody who is going to understand what kind of administrative datasets they have in their agency that you might be able to mine.

This is not a good time to say, okay, from an OMB perspective, from the perspective of the budget, to say, okay, well, we recommend that we do all these new data collections. That is not going to go anywhere. But it is likely -- say if you take the CMS example. There are data right now in CMS that you probably weren't aware of that could be analyzed through their virtual research data center to actually look at much more small-area analysis than we ever would have been able to look at with any of the other datasets that we have because you have got everybody there.

It is a place to start to say, okay, let's look at all the different kinds of things that we might be able to create from the data that they have. We know what indicators we want, so let's now put the focus on the datasets themselves.

And one of the priorities of the action plan is getting agencies to be more complete in their data inventories, which would be someplace that in five years you could go to, if we're successful, and see all the different administrative datasets and they will have metadata next to them that will tell you all the different variables in there. And you could do this from your computer.

But we have been -- the Obama Administration tried to get the data inventories going, and that was 12 years ago since this effort has been going on, 14 years ago, because it was one of the things that they really hit the ground running on and we still don't have complete inventories.

So, what I'm saying is that you could wait for the inventories to get better and then go through them and find the things that you're looking for, or you could say I am not going to go through HHS; I am going to go through an agency and I'm going to really have some folks that really understand what we are trying to achieve help us look through all the different kinds of data -- you are basically incentivizing the agency to start looking through their data to find very specific sorts of things. Then it is easy for us to say to FDA, for instance, we understand you have this specific dataset, and this specific dataset would be really good to get on the list to get into the FSRDCs. Or we need to do some more work, it could be linked data that we're putting in through the CMS portal.

But it's difficult because the OMB effort is up here, and it's difficult for us to really help on a detailed level unless there are certain -- here are the

administrative data sources that you want our help getting into the facility.

DR. PHILLIPS: So let’s say we are at the step where we have identified that we know the source for 80 percent of these measures, and we just need a vehicle to get them in one place or to get one analytic capacity to push them out of the FSRDC, or the VRDC in this case. Maybe the data can’t be released but an analytic product of the data at a small area can be released. We know where they are. We know which agency, we know which department has them.

What is the process for them getting them brought -- under a use case -- to say we now need these producing this information?

DR. SCHWAB: The Department of Commerce, on OMB’s behalf, just published a request for nominees -- Under the Evidence Act they have the national data research repository thing, so that was a recommendation of the bipartisan committee. And then the Act itself said the next step is for you to put together a FACA committee to advise what this looks like and how it could be used and how people could draw on it.

And so, in the last week, Department of Commerce published the request for folks. We have sort of delegated

to them the recommendation because they have a lot of FACA committees, and they have a very strict process for looking at representation and all of that.

So I would encourage you -- if I didn't forward you the link I apologize and I will -- make sure that you have not just one nominee but a couple of different nominees with different sets of expertise, because if they have a lot of people that are similar to your favorite, then you have a lower chance of getting somebody in than if you have people representing different vectors that Commerce needs to consider to put together the FACA committee. So that is one place that you could start getting the local, the need for small-area statistics known.

Eventually, the vision for the center is not that it hold all the datasets; it would be more similar to what you are talking about, Bob, where they would have an analytic -- they would have to run some analysis to produce a certain set of indicators, which would be the output. They wouldn't be the ones holding all the data. They would reach out and say you have identified these datasets and they are going to reach out and, with the algorithm you have given them, generate these data and let you know where

sample sizes are too small and these counties are, whatever, and provide that for you. That is the long term.

In the short term, we have a pretty active group for the FSRDCs that Nancy Potok has been running, who is our Chief Statistician until the end of December.

Also, I think two ideas there -- any ideas for filling that spot with a new chief statistician? I am certainly open to any ideas that you want to give me at any point in time, not too long, like in the next month or so. I don't know what the timing is going to be for the hiring, and with the government shutdown and the election and everything else, I don't know whether we might be six months without somebody. I am hoping not.

If you have any ideas let me know so that we can make sure that when things get announced, we send them to you and we can know why you think these people are great. For now, the group will continue to be run and there are representatives currently on that group that include committee members outside, and I think they would be open to a list of five datasets that you are particularly interested in getting into the current centers.

And then you would have to provide an academic that would write a proposal or you would work with an academic to write a proposal to go into the FSRDC and run

the analysis for those. Again, sort of a demonstration of proof-of-concept in using some of the administrative data that you haven't had access to before. That is one way to think about it.

DR. PHILLIPS: We actually have that project set up. We just may need to align it with the measures we're looking for with Census. Other folks on the phone who have questions?

MS. HINES: Bob, do you want to just say at a high level this project that you're working with through your organization?

DR. PHILLIPS: The Census Bureau has for several years been wanting to bring clinical data in connection with Census data to try and understand how clinical data might help fill gaps in small areas for understanding the health of those communities. And so, with a national registry that I run we are bringing those data into at least one FSRDC with Census data, with ACS data specifically, to try and see the utility of that on their side.

On our side, it's an interest in getting to even smaller-area data to try and validate and re-test some measures of ecological social deprivation and social risk that could inform clinicians on their patients' lived built

environment. So it's a two-way effort to bring those together.

But it might be, because Census has other data they may want to bring to that process to test, it means that we might be able to bring other datasets that have those elements if we're looking at community-level measures. I may go back and try and declare that a proof-of-concept for that.

DR. SCHWAB: Are you working with the LEHD program at all? They are the ones that have put out some of these more community-level indicators and have done the most work with local areas to get local data in. Are you also working with those folks?

DR. PHILLIPS: Yes.

DR. SCHWAB: Excellent. I think that is your best bet. The problem in working with Census is once you are linked to the Census data you have an even higher hurdle. You are under Title 13, so getting access to that data depends on, obviously, your continued relationship with them so that they keep producing what it is that you want to produce.

I'm glad that came up because one of the other things that I thought about when looking around on your site is something that we have had issues with over the

years, and there have been at least two other efforts in this area. There was -- I can't remember the name of them, but there was state of the U.S., that one, and then there was the guy -- was he the one that was running it on his own over on H Street? I think it collapsed. But I think he had asked for the National Academies' input.

And what was so nice about what he was doing -- and he used BRFSS data and other datasets -- is that when you pulled up the numbers there would be a graph, and you would hover your cursor over and you could actually get a feel for what are the sample sizes in these groups and what is the variance and so how much trust you should have.

It's like you've got Gallup data as one of your sources, and the limitation of Gallup data is that they have a very small response rate and they may have large numbers but, obviously, they don't have good coverage, and you are sort of relying on them to say, okay, well, if a county doesn't have more than 20 people, but the sample wasn't chosen to be representative of counties. So, having the ability of the person to actually understand what those data mean I think is going to be important in pulling in administrative data.

And the kinds of data that we are now talking about pulling in, it's being able to, okay, we generated a

statistic for that area, but what does it really mean because we are at a much lower level of aggregation than either the sampling or anything that the administrative data collection was really designed for. It doesn't mean we can't use it, but it's a question of how do we message for people who aren't statistically literate, but even if there is a number, the utility of one number might be very different than for a bigger county.

MS. LOVE: I am with the National Association of Health Data Organizations in my day job, and last week we heard from Census who, through the Enhanced Data Initiative, I think is linked to what you are talking about. And they are taking one state's administrative data and actively working right now on linking that, and there seemed to be some interest in other states with their vast trove of emergency department, inpatient and claims datasets. And this is sort of the prototype. I think some of those linkages may make their way into the Federal Statistical Research Data Center eventually.

One of the things that seemed awesome to me was that it took about two years to work through the MOUs on both ends. I am hopeful that after the first or second states come in that those could be streamlined a little bit, because we are letting a lot of data sort of lay at

rest that should be put to work for these indicators at the local and federal levels. So I think we are going to see more action if Census comes to a positive conclusion with the linkage of the emergency department data with some of their vast warehouse data.

DR. SCHWAB: That sounds excellent, and I know that NCHS is also, with its healthcare studies, trying to figure out how to harness the vast electronic health records access that they now have as part of -- you know, that being an option to show meaningful use for the hospitals to get their reimbursements or their payments.

NCHS has access, but the question is what kind of a structure is necessary -- and I don't mean physical structure, but you need people and computing power to pull all this together and organize it into something that you can start mining. And those are data that are here.

And one recommendation that maybe does belong at the HHS level is how do you get all the other agencies in HHS to pool their resources so that these electronic health records can be mined not only by one agency but by all agencies. But the amount of resources it's going to take to figure out what to do with this, how to pull in all the different hospitals that are providing data, what that

actually means and put it in a form that queries can be done -- that is huge.

But that is sitting right here on the horizon.

MS. LOVE: I just want to put in one more plug. I think if we do stronger linkages between what's happening with those initiatives locally and NCHS, lessons learned, shared services, that will save us all a lot. I just don't want us all to reinvent the wheel in different siloes.

MS. HINES: Someone who is listening live from the public just wrote us and said it seems that the federal government departments are required under the Evidence Act to develop learning agendas and data inventories. Are these distinct from the steps you are describing under the Federal Data Strategy?

DR. SCHWAB: The ideal is that they will eventually draw together. This is the first time that the agencies have been asked to do the learning agendas, so they are still trying to figure out what this means. As I mentioned, we have new people who just were given new instructions a month or so ago and now one of their first tasks is these learning agendas.

It is not distinct; it's just not well developed yet. What I was suggesting were some things that, instead of waiting until agencies get good at doing their learning

agendas, there might be some hopscotching that you could do to get to your specific areas.

But yes, the way that the Federal Data Strategy is written, it's designed to mesh seamlessly with the requirements of the -- the Federal Data Strategy is one of the ways in which we are implementing the Evidence Act. So, as you probably saw, the first Evidence Act guidance that came up was really about, okay, these are the responsibilities of these different people; this is what those learning agenda are. That was sort of Step 1.

But we are moving ahead in parallel with the Federal Data Strategy putting together this inventory because that is going to be pivotal, but we are trying to do as many things in parallel as possible. From the outside, it might not seem -- okay, we are slowly marching down the list of what's in the Evidence Act, but we very much view the Federal Data Strategy as a way to implement that, because the Evidence Act ideas influence the Federal Data Strategy. Now it's a matter of moving them together.

But again, moving the monolith of the federal government is hard, moving a department is hard, as far down as you could get to very concrete things that an agency can submit through a learning agenda so that they get the idea that, okay, this is exactly what belongs in

the learning agenda and it will be useful for everybody, and that gets in.

DR. PHILLIPS: Margo, thank you very much. Quinn, thank you for being here, too.

DR. SCHWAB: She is probably going to be your right hand when you actually start thinking about specifics.

MS. HINES: We are going to reconvene at 12:45 and launch into talking about the year ahead, starting specifically with privacy and then going into our work plan.

(Luncheon Break)

AFTERNOON SESSION

Agenda Item: Subcommittee on Privacy, Confidentiality, and Security

DR. STEAD: We are going to reconvene. Frank, we have your PowerPoint.

DR. PASQUALE: That sounds great. Feel free to interrupt if anyone wants any clarification or you want me to speed up, because I know we want to have time for discussion, and I will be mindful of that.

MS. HINES: Frank, this is Rebecca. If you could talk a little more slowly because the audio isn't crystal crisp and we can make sure we get everything you are saying.

DR. PASQUALE: Sure. Let's just start with the next slide. You can see that we are beginning with the Beyond HIPAA journey. I recall earlier in the day Bill noted that he and Linda Kloss have gone through the Beyond HIPAA report and have been spreading the good word about this report. You can see it was a very deliberative process for the Privacy, Confidentiality and Security Subcommittee. I will just call us PCS for convenience sake for the rest of the presentation.

There was a project scoping and initial hearings. Then there was an environmental scan to understand what are

the new threats and new opportunities here both in terms of possibilities of people's data being breached, misused, used against them in ways they don't understand, but also new possibilities for new forms of technology to promote privacy, confidentiality and security.

The focus then narrowed down in 2018 to the intersection of the regulated and unregulated worlds, and this is going to be a theme of the rest of the presentation today, this very troubling fact where many, many patients, probably the majority, think of something like HIPAA and confidentiality protections as running with health data, but you have a legal framework where that is not the case, but that HIPAA is covering covered entities. And there are so many entities out there that can both access your health data or can possibly get your health data via your oral permission or can infer health status from individuals from things like shopping habits, tremors in one's hands, even some of the new studies saying that the tremors in your hand when searching on a website can be predictive of Parkinson's disease six months out just from web search data. So there are just so many new forms of threats in terms of privacy and security threats to individuals out there.

Then, in March 2019 there was a working meeting to develop a framework and then the report in June 2019 went out, that report on Health Information Privacy, Beyond HIPAA and Letter to the Secretary.

As we have been talking in the subcommittee over the past few months with respect to 2020 areas of focus for the whole committee and also for PCS, one of the things we were thinking about was artificial intelligence in healthcare, and as a committee we had that comment earlier with respect to the data strategy and we have been thinking a bit in that area, and I will have later slides that will get a little more concrete here.

But for now, just some ideas are about the collection of data that may be unexpected via medical devices, via apps, via things that we interact with daily, mobile phones, mouse movements on our computer, et cetera. And thinking about how does AI change the privacy, confidentiality and security landscape. We also talked briefly about privacy and genetic information, so, new frontiers there with the aggregation of massive amounts of generic information in certain commercial databases.

A second area of focus is with respect to electronic health records and interoperability. Here, I think one of our roles is to think about unexpected

consequences. We do have clearly a policy promoting data liquidity, interoperability, stopping data blocking, but we have to also think about what could be unexpected consequences, and problems there.

We also had a brief discussion of consumer education, but we also have to think very deeply about moving beyond that because, as many of us realize, people are busy, a lot of them do not have the time to properly be looking after massive amounts of health data about them.

I recently saw a study that said there were over 4,000 entities that maintain consumer scores on individuals, and many of those could be health scores. Even if there were a robust opt-out regime, which there is not, and even if people really were devoted to opting out, that would mean that they would essentially have to go to 10 websites a day for an entire year to just opt out. So this is one of those areas where you have new emerging threats and data collection on the horizon, which is deeply troubling and really requires a fundamental re-think in many areas.

In terms of the time line for the Privacy, Confidentiality and Security Subcommittee, one of the ideas was to -- our initiative concretely, is to be determined. I will give you some of the more concrete angles on that in a

bit. But one idea is to really drill down on this problem of -- and it was mentioned, by the way, in the earlier OCR presentation this morning -- is this problem of HIPAA not running with the data. The idea here would be that, as through this quarter we have been sort of framing that issue of what are the next possible steps in a healthcare world where HIPAA doesn't run with the health data, where it covers covered entities where the health data that can really matter and really affect someone adversely is being often developed, cultivated, in this non-HIPAA covered space.

I have even heard some discussions of people saying that it seems as though we possibly could have a situation now where entities covered by HIPAA face higher regulatory burden than entities not covered by HIPAA, but the entities covered by HIPAA are the ones most likely to be using some of this data for the patient good and the ones not covered are the ones where people are really quite scared about the possibility of scores or other information about them affecting parts of their daily life, either discovered by their livelihood, access to credit, et cetera, or even by acquaintances, friends or family members. So that is I think a really interesting issue in sort of framing the HIPAA and non-HIPAA divide.

Another possible way to move forward is, in Quarter 1 of 2020, to design a workshop and issue invitations and host that. Then, by the second quarter or summer, compile the findings, frame the issues even more clearly and, in Quarter 3, fall of 2020, really be thinking about drafting and reviewing the report, and then by the end of 2020 presenting the report for approval by the full committee with some recommendations.

I know during the OCR presentation we heard about work on the Hill and other very important policymakers weighing in on this, and I think we really can have a good voice that both builds on our past research, on our past reports, and also makes us as members of the committee I think a more vital voice in the future of aggregate healthcare.

Some of the audiences that we really want to hear from going forward are consumer-facing organizations, those who are dealing with the patients, patient advocacy groups, other types of groups. Providers, what are the challenges and opportunities they see? Payers, policymakers. And other stakeholders could be a very wide range because I think that there are many entities out there that are making new conceptualizations of the health security and privacy problem but are representing individuals that are often not

heard in the policymaking process from marginalized communities.

I think particularly of the work of (indiscernible name) and Michele Gilman at Data & Society, which I think is very rigorous work that is both concerned about privacy threats to marginalized communities and also is very concerned about how the surveillance gap, people not being in certain systems, can hurt them. So I think getting that sort of input from some civil society groups would really enrich the dialogue here and help us take our work product to the next level.

In terms of just the nuts and bolts procedure here, we will be looking forward to a very detailed plan for this workshop, and of course, in our conversation today I will be taking notes about what people think should be included or not included in such a workshop, and thinking further about what happens in a world where we have new opportunities and risks out of new forms of health data and new ways of transferring data, getting the subcommittee and discussion and sign-off on that.

Conference calls with the outside participants, because we want to be sure that we have everyone on the same page with respect to what is the scope here, what is the scope of the committee’s work and what is outside the

scope, and pre-meeting materials to the workshop by February.

I think it is a little ambitious, but I think we are giving ourselves some time there. Also, I just can't wait to have -- I know at least one of the new members, someone whose work I really respect and is very interested in this area and have learned a lot from, so I definitely want to make sure that new member involvement is key there as well.

Just to note, in addition to the slides, we have another set that is going to be cued up and is just going to put this forward a little more about what would be some concrete ideas about the kinds of issues that come up and this tension between the over-exposure, hypervisibility and under-exposure, under-representation of databases, so I will go over that.

Again, the broad issues for discussion which I mentioned earlier are in different forms. Also, one thing we want to be sure to coordinate and think about is what exactly is the FDA doing with respect to things like mobile mental health apps, which I will get to shortly, and other privacy and security guidance from other agencies. Thinking about how did AI changes things, for example, by making things potentially more easily re-identifiable. Are there

other threats and opportunities there? And genetic information.

One way that I want to frame things here is that the stakes are very high because we really face this fascinating tension now between governance of artificial intelligence and governance by artificial intelligence. I used the example on the slide of credit scoring, particularly on the right-hand side of the slide, as an example where really our scoring systems have developed, especially when you look at the rise of fringe and alternative data in extremely complex financial algorithms.

These types of scoring systems are also having a very big impact on the healthcare system. There was recently a very compelling discussion in Nature by (indiscernible) Benjamin, of a healthcare allocating algorithm, an algorithm that was being used to decide in terms of how much attention certain individuals should get. Her concern was that essentially this algorithm had a disparate impact on minority patients. I can explain in questions and answers how that might have occurred.

But I think it is really critical that when we get very esteemed researchers like Benjamin offering these very deep critiques about problems of AI governance as it is being used in the healthcare system, that advisory

committees and other leaders within the government are able to respond to that. We have examples from us, from HHS, from NIST and abroad as well, and I think there are many good examples of ways of developing AI policy guidelines.

I actually just went through 40 different AI ethics law and policy guidelines issued by corporations, governments and civil society entities, and there are good data visualizations of these, and all of that can be great and needs to be I think digested and presented to our stakeholders in an accessible and compelling way.

Some of the issues that come up in terms of data collection and other issues of data equity and inclusion include machine learning in dermatology and learning healthcare systems. I will go over those briefly in the next couple of slides. But just on the horizon, there are some really critical issues that I think are also going to call upon our expertise either in 2020 or later on.

One example that was brought up in JAMA Dermatology recently and is also a concern in Eric Topol's very interesting book, Deep Medicine, is the possibility that you have AI becoming either a closed tool standard of care or the standard of care in terms of its deployment in various pattern-recognizing medical settings, for example, in dermatology, and an emerging concern already in JAMA

Dermatology that the databases are not inclusive enough to fully do justice to minority groups or to achieve success with minority groups, as with other groups. And one of the concerns here needs to be, I think, one is the broader data policy here, other ways for those who are experts in data policy to help intervene to help address this problem.

There are events infrastructure for health collection standards, and I think that there are some situations in state privacy cases where federal standards inform discussions of the standard of care, and perhaps this is an area, too, that could be a topic of further discussion in the future, perhaps not in 2020 but afterwards, with respect to this type of standard setting.

I also have looked to the authorized testing and certification bodies for electronic health records as one example of a precedent for government involvement in setting an agenda for safety and efficacy with respect to devices that are used and with respect to records, and I think there is a logical step from there, from that sort of precedent to developing some ideas about further types of certification or other ways of ensuring advances in this area.

Another example of health data collection that people may not be aware of comes up with respect to things

like automated mental illness flags. There is a controversy in the UK over an app developed by Samaritans Radar which was designed to -- You could download it onto your computer and have it tied in with your Twitter feed and it will be constantly monitoring the tweets of those whom you follow, and then the idea behind it was that it would alert you if one of those people had language in their tweets that seemed to indicate suicidality.

And so this is an app that a lot of people found creepy. They found it quite troubling because they didn't believe that part of their Twitter experience should be enabling people who are following them to essentially be combing through their tweets for signs of mental illness and then to be flagged and possibly have an intervention by that person or have the person who was following them call authorities, in a worst case scenario.

We now do have something like that, by the way, with respect to Facebook's algorithms for detecting suicidality. And according to Natasha Singer and Mason Marks, in both journalistic and academic work there have been over 2,000 interventions sparked by the Facebook algorithm in that area. Again, the question arises what is done with that data, where does it go, do people deserve

some right to understand about these sorts of shadow health records being devised without them.

With respect to ways forward, I think the VA program called Project Durkheim, on the right side of the slide, does something very similar with respect to suicidality data and social network data and does offer something on the way forward in terms of its requirements for opt-in to be part of that program and, at the very least, other rudimentary forms of notice that I think would be wise in some of these areas as very large tech firms and other entities with large amounts of data start entering more and more spheres from finance to healthcare.

Another thing to consider is with respect to, say, FDA-approved opioid use disorder apps or other apps that are similar in this area and to what extent is data entered on such apps leaking. There is a law professor, Laurie Andrews, who has examined ways in which certain apps -- I am not saying that this particular app raises this concern for me at all, but I am saying that apps in general that might be even prescribed, as this one, that there might be some inability of users, patients, et cetera, to understand the risks involved.

This slide shows part of the app and part of the type of cooperation there. Again, in this situation you do

have pretty clear business associate relationship because of the app being described by a healthcare provider and (indiscernible) provider, but I still think there are some very interesting questions raised even beyond that with respect to, to what extent does an app itself signal forms of health information to other entities that might have access to the app or the marketplaces were you need to download the app.

I think these concerns are even more pronounced when you have apps that might be direct to consumer, DTC, for example, Woebot, which might be an example of a very large class of apps where, again, -- leading the way in terms of thinking through what are some of the implications with respect to where does this data go, how are individuals interfacing with it.

Some of the ways in which I would categorize concerns is I would say there are both algorithmic accountability concerns, and the most basic of those is privacy with respect to notice and consent. But I also think, just in terms of data and statistics in general and thinking about vital and health data, a lot of people have been asking questions about do such bots, are they capable of reaching a broad spectrum of potential users. These are the types of issues that we discussed earlier with respect

to minority skim and the dermatology apps that are going to be potentially arising in the area of mental health.

I also think with respect to data security, safety and effectiveness that there are some data-gathering and sharing standards that are critical. One that made a very big controversy last year was an app that did not follow mandatory reporting rules with respect to disclosure of child abuse.

And one of the things that I think we need to think very deeply about is how do mandatory reporting rules in some of these areas interact with the forms of health advice. How exactly are these laws drafted at the state level? Moreover, are there forms of disclosure that ought to be mandatory or recommended to users who may be drawn to these apps? One of the main draws of many of the therapy apps is that you can tell your deepest secrets to an entity that will not know you, so this really needs attention with respect to privacy and accountability online.

Another issue, too, is in terms of potentially biased data in general. Are there ways of auditing for what computer scientists often like to call ground truth in an inquiry, and the best ways to invest in knowledge acquisition, maintenance and analysis?

I just want to put in a little plug for something called Fairness, Accountability and Transparency in Machine Learning, which has done a model for algorithmic accountability for computer scientists. In terms of thinking about people that we engaged with, I know that my work on this project called Transparent Data Mining for Big and Small Data was very educational for me in terms of needing to interact with people with more of a focus on the computational side of things in terms of what is possible and what is not in these systems. And I think in the future, hearing more individuals from this FAT-ML community which has an annual conference -- and there are other conferences now emerging in this area of algorithmic accountability -- it would be wise to keep this group on our radar screen.

This is just a sampling of relevant discussions. I just give some examples here about how, with respect to IBM and Microsoft, each of those firms I think has done very interesting work with respect to talking about black box models, talking about bias. Michael Veale is a researcher who has talked about public sector machine learning, learning how for data that’s being put in the public sector there are special considers there.

This is my final slide. My basic bottom line for my presentation today is that responsible AI development really is a critical social aim, and the big focus really needs to be on data. AI development is data intensive. There are lots of overlapping legal regimes that govern data collection, analysis and use.

And we need to not merely educate the public about inaccurate and inappropriate data, but I think we also need to think about policymakers because there are so policymakers who really I think are trying to go beyond what I consider a completely broken notice and consent paradigm now online and elsewhere. And with respect to this type of issues that we are seeing emerging and now even solidifying in these areas, advisory committees can help disseminate the best practices.

So I hope there is interest on the committee with respect to the relatively narrow focus of the 2020 work about the future of how we deal with a world where more and more data is outside of the HIPAA coverage, and moving forward on how to deal with particularly the problem of people being able to download lots of health records onto apps and then suddenly finding that they don’t have any protection. What exactly needs to be done there?

Also, what are the states' best practices with respect to health privacy?

And then, after 2020, to get some feedback in terms of what are the types of things that are on your minds about what PCS should be addressing beyond that issue of the unexpected negative consequences of data liquidity in a world where HIPAA does not follow the data.

With that, thanks very much.

(Pause)

MS. HINES: Just as you finished you couldn't hear us anymore. Bill was talking to you and you didn't know that he was talking to you, but I think we have the issue resolved. Sorry, Frank.

DR. STEAD: We have got to figure out where we are and how to best use our time. We have about five minutes left in the block that was targeted for the PCS discussion, and then we shift over to the workplan discussion. Fortunately, the two are sort of continuations of one another.

From my perch, Frank, what we probably should try to do is focus in on what's realistic to try to consider as part of the draft timeline that Rebecca and the team have up on the screen now, rather than the sort of general

discussion of the two presentations. Is that where your head is?

DR. PASQUALE: Sure, that sounds good. If anyone wants to write me afterwards or call me, we can talk. I am totally fine with narrowing that focus, yes.

DR. STEAD: I will provide thoughts from my perch. The committee is most effective when we go through a process that involves a fairly careful scoping followed by a scan of the area that we have decided to focus on, using that to frame our thoughts about potential recommendations or how a panel in convening might inform development of recommendations. Then doing that and trying to see where that leads. I know you are sort of familiar with that process because you have seen us use it a fair amount.

With that frame, it seems to me that if we want to do something in this upcoming year, in many ways it has got to be pretty carefully anchored in our Beyond HIPAA Privacy report. That exists. It provides a framework.

I was just thinking one possible way forward would be to say let’s look at the issues that you described in your first presentation around potential untoward consequences of meeting the access, interoperability, policy priority and approaches that would be responsive to that, and we could actually use that as, if you will, a

case example of trying to apply the policy framework. That might be one way to anchor ourselves in that work to align the questions we are trying to pose with ones that ONC and OCR think will be most helpful at that intersection of interoperability, giving patients access and privacy.

So we might be able to come out with useful recommendations in that space, and that could serve as an example of use of the framework, much the way we viewed this year's ICD-11 work as an example of applying the criteria for adoption and curation of named TNV standards. We basically viewed this last year's more focused work -- although it's hard to believe it really was focused -- as a test case or a demonstration case of our previous recommendation. So that might be one way of targeting this.

Let's stop for a second and see whether that approach might resonate with you or the committee, or whether, given that sort of thinking about how we frame these things, whether there's something that seems equally actionable. From my perch, the AI work, although extraordinarily informative, is something that is going to take significant pre-work I think before we would be in a position where we could add much of value. I will show you my scar tissue. I think that would be much more likely to

be something that might be on the plan for 2021, possibly even 2022, rather than 2020.

Those are some of my thoughts.

DR. PASQUALE: I am in complete agreement about that. I was bringing up some of that material as just very much a trial for 2021. I think that for 2020, absolutely, I really like your reframing of it as an application of those very good principles and ideas that are in the Beyond HIPAA report.

DR. STEAD: Let’s open that idea for questions or discussion by the committee. Let’s test that, if that would be useful, or if the committee has an alternative approach to success that might be equally targeted and getting traction.

MS. HINES: Is everybody clear on the use case that Bill just laid out? What he was saying was the little intuition thing -- In the slides that Frank just showed, the first set, he was talking about the untoward consequences of too much access to patient data without their awareness of it, interoperability, and to use this as a case example to apply the framework report that this committee released in July, which had the model. We have this model now, and this could be a use case, this meaning the presentation before the AI presentation, as a use case

for applying the committee's own model, just as we did with the ICD work using the other framework.

DR. STEAD: I would keep it as narrowly focused as we can on how we can help frame and address the privacy concerns at the intersection of interoperability and patient access. I would keep it there as the next thing we would try to bite off, because it seems to me, if I understood Don's comments correctly yesterday, that is right in their focus. And it seems to me it matched up with what we heard from Tim Noonan about OCR's focus. So it seems to me that would be right in that sweet spot if we could try to keep it focused enough but it would be still bigger than a breadbox, but the Beyond HIPAA framework gives us the background. As long as we stayed with applying it, we would have a prayer of doing something.

MS. LOVE: So, not having that report and just trying to draw on my memory, I have no problem with applying the framework. But I am trying to get ahead of it and say how that would be applied. The thing that keep me up at night and I hear about is moving even public data faster, because it is slow.

So would that get at new ways of sharing the data, sharing platforms and connecting datasets across the

sectors? Would it be along those lines? I am just trying to figure out what the framework would be applied to to solve.

DR. STEAD: My thought would be it would be to access -- a patient’s access to their health information via apps supported by interoperability. That would be the space that I would suggest we target first, given what I think I have heard from both ONC and OCR. That would be a narrowly focused space.

DR. PASQUALE: I think I have lost the sound again. Can I jump in on that question?

I think one paradigm case that is really interesting and difficult here is the person who, say, has an app and they are keeping track of their fitness or other more intimate activity or health-sensitive activity with the app and they really don’t realize all of the different elements of where that data could go, et cetera.

The second paradigm case would be someone who is under, say, a view, download and transmit requirement or other things that we want to see in terms of data liquidity, has that information and is approached, once they have it on their phone or their cloud system, whatever it might be, is approached by another entity that is not covered by HIPAA at all that says hey, let us download all

of this and we want to analyze it. That's another area where I think that is a second paradigm case.

One thing in terms of scoping that we might want to think about is are we only concerned about the consumer -- and here I am inspired by Nick Terry's very interesting 2009 Drexel article about personal health records where we was very focused on consumers, and I think that is one -- that would be certainly a narrow scope and very valuable project.

The other side of that would be do we go beyond that and think about the situations raised by, for example, new forms of business associate arrangements where you might have mass data transfer by a covered entity to a non-covered entity with an instruction, we want to see big data analysis in hopes of better improving quality or better improving treatments in the future. As Pam Dixon's presentation laid out yesterday, people will say it's not research, it's not one of those rules, it's really not TPO or a prong of TPO.

I guess one thing to clarify with respect to scoping would be should this type of application of some of those Beyond HIPAA principles only apply to a situation where the big concern is the consumer who doesn't realize that once they have the data, when they transfer it, by and

large HIPAA is not following that data because they are not a covered entity? Or do we go beyond that consumer scenario and also address the stuff that has just very recently been in the news about healthcare systems and others wanting to engage in very novel partnerships with very elite, cutting edge AI companies with respect to massive datasets?

MR. COUSSOULE: I actually like those ideas. We talked a bit about this in the subcommittee. If we think about it as what I would call putting natural extension to the information and high-level recommendations and challenges outlined in the Beyond HIPAA report with some very real practical challenges today that are happening in the marketplace, I think the idea of attacking the AI component of this to me is almost a natural follow-on to that. Because the reality is the data -- part of what makes AI valuable is lots of data, and understanding the risks of where the data is and is not I think is almost essential in the rules around that before you even tackle the AI part. I think you would almost have to do some of that first anyway.

And I do think we can make progress. I think it ties in with both a number of both regulations that are either currently drafted or being written, some of the legislation that’s coming in. I think tie-in-wise, it’s

pretty good as well, and it's something that I think would fall under the bailiwick of what this committee can be effective at getting.

MS. SEEGER: One of our obstacles is timing and where things are with rulemaking and other things, and I am very worried that your work is not going to sync up with efforts that are already underway.

Just from the perspective of consumers and health apps, helping them understand APIs, et cetera, ONC and OCR are working collaboratively on an education campaign for both healthcare providers and for consumers. I just think that we might have some timing concerns where the subcommittee's work would not sync up with timelines.

And with respect to AI and healthcare, that is all I have been living and breathing this week and all I'm living and breathing right now. Going back to where we were two years ago with our hearings on de-identification, the world has changed. The committee put forward some recommendations but I think we are seeing now an issue with stewardship, and I think there is an opportunity for the National Committee on Vital and Health Statistics to say something about how data is best used and shared. There is just an opportunity, and it would certainly get a lot of attention. It's tough work, though.

DR. STEAD: OCR and ONC doing the consumer education part was part of what we recommended in Beyond HIPAA, and the fact that it's moving is wonderful.

It is less clear to me what you would suggest we -- how you would suggest framing the question of more explicit guidance or recommendations around data-sharing practices over what we have done. Can you unpack that?

MS. SEEGER: I think you have made some very good recommendations to the Secretary and the Department, but perhaps there are some other recommendations that could be made *vis a vis* guidance that you have provided to users on other issues -- maybe putting a work product together based on your knowledge, skills, expertise in this area collectively and putting out a white paper or some other type of guidance to the industry. Just a thought.

MS. LOVE: Getting back to my inarticulate suggestion of data-sharing platforms, one of the things that I have been forced into is thinking more broadly about how we share data, and it has come up -- and I spoke with Pam a little bit about it yesterday. Some people call it honest broker but she called it white hat intermediary.

But that is something new to me, maybe not to all of you, where there is sort of a firewall cloud where data goes in and AI and other things are done to it and it goes

back, but it is more transparent. I think for public health it may be an answer to some sort of data exchange that we haven't really thought about. In the private sector they are just sucking up all the data they can get and doing things that I am not sure what they are doing -- well, I think I know -- and monetizing it.

But for public health, what would a different kind of data exchange that we don't have today look like? Pam called it white hat -- I think she said intermediary. He's a good guy broker that is not selling the data but is taking in public health data -- as I understand it. I just last week got introduced to this concept.

And University of Colorado is wanting to do a test bed; they are doing a platform where you can take in a HIPAA-protected dataset and exchange it with another state or another player that also is operating under a set of rules, but that white hat intermediary is bringing those datasets together in a way that is clearly defined, MOU'd and everything else, and then sending it back out without revealing identities. It is so complex and I'm not doing it justice.

But that is a new way of data exchange. When I said new data kinds of platforms that I was asked to look into, and Pam was very helpful, that is happening. They are

out there in the academic world trying to get to public health. We know what Google and others are doing. We think we know. But it's a little different than that. That's a data broker. This is a little different.

Does that make sense?

MS. SEEGER: It does. I think that we heard about those practices in the hearings a couple of years ago, and this practice of match-backs has been on folks' radar now for maybe the past five years. How it's applied in healthcare probably started up out of pharmaceutical work, but now it is certainly common practice and becoming more common.

MS. LOVE: So then West Virginia can send their data off to be linked with a neighboring state's without either party having to touch directly the data and get back what they need. These are things that maybe we are just waking up to in public health.

MS. STRICKLAND: I started down a path of thinking that we want to protect the consumer, but we can only go so far because everyone has free will. If you want to let your data go, then your data is going to fly. But the only thing we could do is, for those entities that are the covered entities, before the data crosses their firewall, and knowing it's going to a non-covered entity, if that were to

flash a warning to say, hey, just so you know, this data is now not protected under any regulatory privacy, whatever.

That to me would be compelling because the person who is leaving is to protect that data, and if they know it's going to cross over to a non-protected entity and if they can tell the consumer and the consumer says okie-dokie, let it go, there is nothing more we can do at that point. But I don't know if it is feasible that that could happen or not.

DR. PASQUALE: I think that, with respect to one of the prime goals for me in terms of doing the scoping exercise, bringing in stakeholders and bringing in experts, is to look at a wide variety of options and not necessarily to prematurely close down the discussion by saying that there's nothing we can do, there is nothing beyond X or nothing beyond Y. One of the prime goals for me in terms of doing the scoping exercise, bringing in stakeholders and bringing in experts is to look at a wide variety of options and not necessarily to prematurely close down the discussion by saying that there's nothing we can do, there is nothing beyond X or nothing beyond Y.

I think that -- particularly because I have been in consultation with several senators' offices and members of the House of Representatives and others, wearing my hat

as an academic, and there is a lot of energy with respect to restrictions on use, restrictions on applications of the data, other types of issues with respect to very suspect uses an applications of data -- I think that really has to be part of the discussion.

Because also I think that existing frameworks, to the extent that you're relying on them -- say it's not just consumer education, it's consumer wealth, it's consumer leisure, it's consumer ability to spend tons of time parsing through different privacy statements or reports on audits about how companies use data. That is not equally distributed in society. It is quite concentrated among people -- and, Frank, I have to raise the class distinction here -- people that are relatively privileged that are able to do that. And if we are not thinking about things beyond that, I think that we are not necessarily leading the charge to develop a health privacy framework for everyone.

With that, I just think that part of what I think is very much the scoping here is to think about restrictions on use of information so that people know that, for example, I may really want to have my face screened as potentially being depressed in a depression screening with my primary care physician if I have given informed consent to that. I don't necessarily want to have

health inferences made about me that are totally uncontrolled affecting, say, credit, housing, education, other life opportunities.

I am seeing a lot of energy there in terms of both internationally and state level and here, and even national level with respect to restricting certain uses of data, again, mainly outside the health sector. This is not about tying the hands of people who are trying to help individuals. It is about I think much more trying to stop uses of data that are totally unexpected, unreasonable, unfair that have deep roots in consumer protection law and other aspects of our legal infrastructure.

MS. HINES: Given Rachel's comment about just the timing, I am wondering whether we should do a little more work on looking at what you are talking about, Frank, what's going on already in terms of rules and other collaborations, and if there is any way to continue with this or whether it would be, at this point, sort of a missed boat anyway.

DR. PASQUALE: I'm happy to put it on a longer timeframe. That's fine. I do realize it's a major, difficult issue.

MS. BERSTEIN: Let me respond a little bit. I agree that the rulemaking that is in process now, we won't

be timely for that rulemaking. But I also think the rulemaking is unlikely to address the things that we are talking about anyway.

The public education piece, as Frank says, puts all the onus on the consumer, and that is not going to solve the problem. Even if you redesign the 6,000-word consent that you get when you sign up for an app, I blow by it and I am a pretty sophisticated privacy user. And everybody else in the room and everybody else I know blows by them, too. That is not the solution. But that is the most I think that maybe ONC and CMS can do right now.

There are other things we might be able to do, and I think those are going to be outside the timing of the rulemaking process, and I think it is something the committee could weigh in on and could be useful for what happens next after this rulemaking, whenever it gets finalized.

DR. STEAD: Frank, you have heard a fairly rich discussion, and I guess I would say that I don’t hear any consensus about how to actually scope the next step. I hear a series of choices and maybe more clarity about what we shouldn’t do than what we should do.

I think all of our scar tissue is that we need to take the discipline to get something that’s written down on

two to four pages that rally makes extraordinarily clear what the scope is that we are considering. That can be a high-level scope or it can be a narrow scope.

What we plan to do with it, what our deliverable will be, will be very different if it's a high-level scope or if it's a targeted scope. If it's a high-level scope, we largely would end up getting enough information to guide some form of environmental scan if we have not covered it in the scan we already did.

If it is a narrower scope, then we would target it at what is the right convening we need to do to get us to a point we can make recommendations.

Those are two very different possible endpoints for, if you will, a phase of the work. We have gotten to where we are really pretty good at breaking up what we do into defined phases. If you look at the ICD-11 scoping document, it may be a useful example to you about how to break something up, because that was bigger than a breadbox and we broke it up in the end into what we have done, four steps now, three and the last one. I think that is work that the subcommittee will have to do and then bring it back to the Executive Committee, and that will tell us something about when we would logically try to sequence it into a calendar.

But I don’t hear us -- I at least would not be enthusiastic about supporting something that wasn’t that well defined, given our limited resources. I am sensing maybe that Maya disagrees with me and maybe Rachel, given their back-and-forth comments.

MS. HINES: I also want to know if Jacki Monson has anything to weigh in with about where we are trying to land this.

MS. MONSON: I am in favor of going where Frank is going. I think that is a big issue. We heard it yesterday and we heard it this morning, and the whole idea of AI interoperability is a huge deal that we are grappling with, and the burden can’t continue to sit on the covered entities to try to figure it out. So I think it is worth some time and further discussion about how we could potentially scope it because it is massive. I do think it would benefit the committee to proceed with something like that.

MS. HINES: After today I will send the subcommittee the ICD-11 scoping document just for a point of reference to see if that is a helpful framework for scoping something out along these lines.

MS. BERNSTEIN: I appreciate Bill’s discussion of high level versus more targeted, but I am also thinking we

have two different topic areas that we are talking about and we haven't figured out whether we can work on them both simultaneously. It would be unusual, let's say, but it is possible. We have done a couple of those things before.

But whether we think it is more timely, appropriate, or just a personal interest of the members of the committee to want to focus on the issues around interoperability and what happens when information is now on your mobile device, or the AI issues that Frank laid out so nicely, of which there are also several things we can deal with. So there is more than one way to cut it.

DR. STEAD: I totally agree, and my sense is the subcommittee has got to do the sausage-making to decide what to recommend. I was thinking we might come out of this meeting landing somewhere, but I don't sense any landing. If I have misheard, tell me. We are at a slight disadvantage because we are sort of trying to run this for Frank since he is not in the room.

MR. COUSSOULE: I would agree with that. I think we have a couple pretty different themes that are part of that, and I think it is necessary to try to craft a manageable scope for either one or both of those and then decide which to pursue as part of that, and that certainly would be something the subcommittee could take on

afterwards, I would assume. I just would argue we are not ready for that quite yet.

MS. BERNSTEIN: I will say we are about to have a couple new privacy members, so that would be helpful I think in doing that work.

MR. LANDEN: I would also agree with the sentiment that Nick and Bill just stated. We have got a tremendous amount of opportunities identified, we have some things that we would like to create, we have some disasters we would like to avoid, and our charter gives a lot of flexibility in this area. So we are gold and we have a lot to build on and the work is already done.

Despite some disappointment that we didn't identify a landing point, I think the subcommittee has Chris to work with and some new input to continue its thinking.

Agenda Item: 2020 NCVHS Workplan

DR. STEAD: Good. With that sort of detailed dive, we will see if we can walk through the overall Workplan in time to honor public comment at 2:30. Rich, do you want to comment on whether this is still looking correct given yesterday's rich conversation with ONC?

MR. LANDEN: Clearly, the desire is to continue moving on the path that we are already on -- prior auth, interoperability.

DR. STEAD: And my sense is that we have got enough agreement that the follow-up call that we will have with Tom Mason and others really can focus in on the approach that would say, if we are going to have the payers look at what of their current high volume prior auth could be handled by the data in the USCDI, we could then use that as a test of could we use Fire and some intersection of Fire with X12 metadata to allow a prior auth transaction plus the API or a series of API calls. And if we could get a demonstration that that could work, then we would be in a position to make a recommendation that we tell the Secretary to inform the industry that we are not going to pursue an attachment standard.

That path is sort of what we talked about. And we could conceivably get to where we have some sort of joint ONC-NCVHS convening in the first half of Calendar 2020 was my sense. And that would move that particular row. Is that what you came away with?

MR. LANDEN: In broad terms yes, that is the pathway. We will continue to collaborate. I know we have a

lean budget year for us, so how we can best leverage ONC and the resources it can bring, that would be ideal for us.

But yes, the idea is to work with ONC to identify a high-volume, relatively low data need prior auth process, whether it is on the physician or hospital side or the pharmacy side to be determined, and whether or not we go through a HIPAA-mandated transaction or we go the exception route, demonstration project route, those details to be worked out as we get more into this, and start identifying the use case that we want to tackle.

But in broad strokes, yes, that is absolutely correct, Bill.

DR. STEAD: Is that enough for this row? Whether that actually turned out to be Q1 or Q2 we would have to see once we got it defined. But what we clearly want to do is get it defined well enough in Q1 that we could do it toward the end of Q1 or in Q2.

MR. LANDEN: Yes.

DR. STEAD: Okay. Then let’s come on down.

Once we make the edit that we have still got to make to the letter -- basically adding the case example to make it a more compelling story -- then is the next step in the Predictability Roadmap work the work that we just talked about?

We have to get the letter out which requires us to write the little case insertion. Once we have done that, then is our work with ONC on prior auth that we just described in fact the next step in the Predictability Roadmap? Or is there something else we would be considering doing in parallel on the Predictability Roadmap?

MR. LANDEN: I think the ONC work, both on prior auth and the larger topic of data convergence, yes, that would be the logical continuation of next steps. Part of the reason I'm hesitating is, depending on the response to the letter we may need to take some additional steps as well, but that we won't be able to determine until we get a response so there's no sense in even penciling anything in for planning purposes.

DR. STEAD: So, what you will then do is say monitor for response from HHS. Okay.

ICD-11, we are done. We have monitor for further steps. We are basically done until the research is done, so that will be a year or two out at best.

MR. LANDEN: Again, we have some finalization to do with the letter that was produced yesterday, but until that research is completed or that communication plan is developed, there is nothing on our plate to do except monitor.

DR. STEAD: Good. We received an initial thing from NCPDP. Where does that show up?

MR. LANDEN: We are expecting one from NCPDP and we are expecting one from CAQH CORE.

DR. STEAD: So, basically, does that cover both of them or just the CAQH CORE? I guess it covers both of them. So we know there are two requests coming in that we will need to respond to in some way.

MR. LANDEN: Correct. And we don't know the timing and we have the head's up from NCPDP -- CORE said December or January, so whether we can combine that as a path that we do need to go to a hearing we will determine.

MS. HINES: Rich, if we add this to the Workplan as an active project, what would the title be?

MR. LANDEN: It would be something under the transactions.

DR. STEAD: DSMO change request?

MR. LANDEN: Yes, DSMO change request.

MS. HINES: Okay. So we will add a row.

DR. STEAD: DSMO would be inappropriate because CORE doesn't go through the DSMO process.

MS. HINES: So change request?

MR. LANDEN: Change request.

DR. STEAD: And we have two possibilities in Q1 to Q2 probably.

MR. LANDEN: Correct.

DR. STEAD: Okay. PCS --

MS. HINES: I think we need to do scoping.

DR. STEAD: I think we are really talking about scoping in Q4, because we are in Q4. We have got Executive Subcommittee calls set up for December and January, so either of those would be a place that something could be floated. And we know we are going to be setting up the agenda for the March meeting, so somewhere along that chain is where that presumably would gain traction.

MS. BERNSTEIN: I had one other thought when we were talking about the prior authorization work. Given the discussion among the panel yesterday and how much involvement there is of privacy issues in what's happening with prior authorization, it occurred to me that maybe the two subcommittees want to work together on that going forward, and that would be the substantive thing that Privacy could be doing at the time that they are scoping out the next topic.

I don't know how other people feel about that.

DR. STEAD: That would be brilliant.

DR. PASQUALE: I would like to just hear a little bit more about it because I realize the committee, in responding to what I was presenting today, really wanted I guess a lot more detail from me, so I just wanted to be sure to get some detail on the prior auth and what the exact content of our work together would be before I would want to sign onto that. Just my two cents.

MR. LANDEN: Yes, if you could add a little bit more to that, Maya, because prior auth would be under treatment and payment operations. What would we be looking for?

DR. STEAD: If you look at some of the things that Don Rucker raised yesterday around it depends on the magnitude of the intelligent processing that you're trying to apply and how much data is involved in that so that even things that are under TPO, although they do not hit HIPAA boundaries they still require appropriate stewardship within the covered entities.

MS. MONSON: I think your idea is a really good idea, and I was thinking that yesterday during the discussion, because so often in the provider space they think that prior authorization, one of the barriers to the data exchange is privacy, so I think the committee and the

PSC group could add some value to helping and collaborating.

DR. PASQUALE: Just to put my cards on the table, I don’t think that it really lands the plane for me in terms of the discussion here. Maybe there is some procedural issue with respect to what is PSC to do if there is not a further -- if it is not approved at this meeting. I don’t know. I think it’s something I would have to think more about, because just procedurally it’s a little difficult to move on a dime from something that the committee worked through and what I thought people had acquiesced to throughout the fall for the presentation today and then just move on the dime to something very different. That is just my two cents.

DR. STEAD: That’s fine. You also have the advantage that you are the Chair of the subcommittee.

(Laughter)

MS. MONSON: I don’t think it was in lieu of; I think it was, well, we are doing the additional work that we need to do on scoping it out. We can probably add value to helping this other subcommittee with the privacy implications of prior auth. That is what I understood Maya’s comments to be, but correct me if I am wrong.

DR. STEAD: Thanks, Jacki. Rebecca?

MS. HINES: I added a row for change requests for privacy, scoping.

DR. STEAD: Scoping, and then I just would put TBD under 20 Q1, Q2. We don’t know yet. Something will be out there.

MS. HINES: I imagine some series of calls during that time. So, data access for communities.

DR. PHILLIPS: I think there is still good reason to continue to work with the WIN network and offer our support if nothing else. They can always bring things back to us if they need us to test or revise or work on things.

I would like to come out of today’s conversation with a clear idea of how we interact with the Federal Data Strategy. I heard the options of nominating people for the FACA for that specifically, potentially identifying a new Chief Statistician and helping get that person in place. I also heard the potential to work with the FSRDC organizing group that the Chief Statistician oversees. But I just wonder if there is an opportunity to keep this conversation going to see if we can give direct input, use cases, more specificity about the data elements that are needed.

MS. BERNSTEIN: I am going to make a comment I forgot to make earlier about a comment that Denise made regarding the white hat intermediary or broker. It occurred

to me to make the connection to what Margo was talking about earlier about the Commerce Department creating what is not now in statute but would be the next phase of some entity that would do that kind of a function essentially in the federal service, and maybe there will be some opportunity to give more detail about those thoughts to that process somehow.

I just wanted to make the connection between what you said and what Margo was talking about this morning because it sounded similar to what the recommendation was in the evidence-based policy commission report that did not get passed into law but was in the recommendations. I just wanted to put a marker down.

DR. STEAD: Thank you.

DR. PHILLIPS: The last thing I would say, Bill, is if I were still going to be here the thing I would work on most strongly is working with WIN for those HHS departmental or agency relationships that they are establishing to move forward these measures. The second would be to work with the Federal Data Strategy to really define the use case and help them see that WIN framework as a use case with high specificity around where the data elements need to come from.

What I am unsure of is where that lands. It still needs someone with agency inside who can use the data to produce the information for the public, and that is where I still remain unclear.

DR. STEAD: My reading of what she told us is that the Federal Data Strategy is really about trying to slowly get the wiring diagrams working in the federal government. I think that she views that as a journey, as it undoubtedly will be, and I didn't sense that she felt that it was anywhere close to a point where it would be thinking of working as a data strategy around use cases. That was sort of my sense.

And what she therefore was suggesting is, if we want to do something in the next one year, two years or three years, that we should be focusing -- and it is not really our role; we could help WIN do this -- but that we should be focusing, making connections at as low a level as possible around a specific dataset and helping the light bulb go off there, that they could make it useful and how to move it someplace. And my sense was she was thinking that that kind of bottom-up would (a) help you with access in the short term, but (b) help light bulbs go off that would actually have a chance of connecting with what they are trying to do as they re-work the wiring diagram from

the top down. And, as a person who does a lot of change management, that would be a reasonable strategy.

But that was my sense. I may have misheard.

DR. ARNOLD: I would like to suggest that I think there is a lot of potentially really good work the committee could do in this area, but I think that HHS is not quite ready at this point. I think the Federal Data Strategy is a really good kind of roadmap, but in a sense it has been superseded by the passage of the Evidence Act, and we are still trying to get our arms around how we are going to implement the Evidence Act given the HHS data strategy and who the players are in HHS, et cetera.

I talked yesterday a little bit about the organizational construct that we are setting up. I think that once we identify a chief data officer, once we get some of the guidance from OMB there will be a huge role for the committee. But I think right now there are too many uncertainties for the committee to necessarily stake out a specific position.

DR. STEAD: Thank you, Sharon.

Then that is really our current workplan as we stand. I think that means our major focus at the moment will continue to be around standards and privacy as we sort of have gotten guidance to do, and we will need to work

with the subcommittees to bring something back. Anything else, or can we turn this over to public comment?

MS. LOVE: I think my problems are so -- I am embarrassed that they are so small. These are big global things and I have no problem with any of them. But the things that I get hammered with on a daily basis are small issues like the national provider identifier, and MPPES doesn't work for any analytic ACO or any of the value-based purchasing things that are going on out there. They are just not working and that is a chronic problem, and people say, oh, you're on the NCVHS; bring that forward, so I'm bringing it forward. But it may be something that can't be done through this.

OPM data is shuttered off from the rest of the world for all-payer claims databases and population looks from that claims data.

And then, how does OMB -- and I forgot to ask this and I may write them. How do they assign value for a dataset? This came up in the Lower Healthcare Cost Act and a few other things. What methodology are they using or will use to assign a value to, say, a state dataset that they want transferred to the federal government at cost, and what is that cost is a big deal.

These are my issues and I think they are too small, but I wanted to just put them on record either in the parking lot for some future work or just let it go, like the movie.

MS. HINES: Any thoughts from other members? Anyone on the phone have any response to Denise?

MR. LANDEN: Just to respond, I think maybe we should pursue that on one of the subcommittee calls and start fleshing that out and just learn more about it and figure out if that is in our wheelhouse or not.

MS. LOVE: The value thing is maybe something in the future parking lot, but how do you assign a sale value or a value to a public dataset?

MS. HINES: It looks like we have some idea on some projects, a lot more clarity, and for others there is more developmental work. We have the March meeting as our next seminal event with four new members coming on in the meantime who will really add a lot of energy to privacy and, to some degree, standards, so I think things will look probably a lot farther along when we get to March.

MS. BERNSTEIN: And just a reminder that we are going to be working on the next tranche of people, and so I reiterate what Sharon asked you yesterday, which is that if you have ideas or recommendations for people who you would

like to be your colleagues on the committee or, for those of you who are leaving, now you know what service is like, who would be able to contribute valuably to this committee, please let Sharon know or send them to me and I will forward them along.

MS. HINES: And we have two more waves in the next 12 months because we have three openings now and in October three major significant contributing members, including our Chair, who will be rolling off after two terms of service.

Agenda Item: Public Comments

MS. HINES: We are going to move to public comment. Is there anyone in the room? Please give us your name and organization.

MS. WEIKER: Margaret Weiker, NCPDP. A couple of items. In regard to your planning for future and doing the NCPDP request, I would anticipate that being done sometime in Quarter 1 of next year. The DSMO request has already been submitted so it would be in the December batch. And then from there, I would recommend that the DSMO meet and get this done fairly quickly so the DSMO could send a letter to NCVHS I would think by end of January, early February.

Last time when we did this, we did a virtual hearing versus a face-to-face hearing. I don’t know how you

all felt about it, but from my perspective and the members that did testify, that seemed to work out pretty well versus having people travel and doing all of the logistics, even though there are logistics in a virtual meeting. I think that worked out well, so that may help win-win for both groups, so to speak.

Another item in regard to the 278 and prior authorizations. As I have said on multiple occasions, the 278 does not work for pharmacy. So, if you are looking to do a pilot to see how USCDI and Fire and the 278 work together, I recommend not doing pharmacies because we know the 278 does not work. We have piloted it, we tried the 278 with the 275 and it just doesn’t work. So I recommend another use case to really see if this would work versus the pharmacy.

In regard to attachments, we need to remember there are also claims and claims attachments. While we may be able to figure out a way to get rid of prior auth attachments, maybe that is the steppingstone to get rid of claim attachments. But I think that is a much bigger breadbox than prior auth attachments, so we may not be able to get rid of attachments at all.

Now, from a pharmacy point of view, we hate attachments, we don’t want attachments. We do things in

real time, in seconds, so we don't like attachments. And anytime somebody says I need an attachment I'm like, for what. What is the data that you need and can't we codify it or something versus putting it in some piece of paper and then sending it along, even if it's a CDA.

Those are my two comments. Thank you.

MS. HINES: Anyone else in the room?

MS. SHEPPARD: Cathy Sheppard from X12. Hear, hear to please not forget about claims attachments. That was also on my list. It is a little premature at this time, but for planning purposes we would like to let you know that we expect to bring change requests to the DSMO next year that would make their way to this group but not in Quarter 1. You can put that later on your plan. But just so you know that is our intention for 2020.

MS. HINES: Thank you Anyone else in the room?

You can send comments on the dashboard or the NCVHSmail@cdc.gov. I do not see any emails to the NCVHS account. Is there anything on the dashboard of the broadcast? None.

At this time I think public comment is completed. If you had hoped to make a comment and missed this period you can always send email to ncvhsmail@cdc.gov. And thanks to all who are listening in the general public. We can see

that you are on and we value knowing that our work is of value to you, so thank you.

Agenda Item: Closing Remarks & Adjourn

DR. STEAD: We will adjourn with once again saying thank you to Bob for your service.

MS. HINES: Yes, Bob, it has been an absolute honor of my time so far on the committee to have had the privilege of working with you. It has been a tremendous experience.

DR. PHILLIPS: Likewise. The honor is mine. The conscientiousness and the level of effort of this group has been incredible and I have learned a ton, so thank you.

MS. HINES: Before we close, I want to make sure we properly thank those who made all of this possible, Marietta Squire, Geneva Cashaw, the RLA logistics team, and Maya Bernstein for making sure that we could meet in an appropriate space. Thank you all.

(Whereupon, at 2:35 p. m., the meeting was adjourned)