



**HIT Policy Committee
Privacy & Security Workgroup
Final Transcript
September 21, 2015**

Presentation

Operator

All lines are now bridged.

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

Thank you. Good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy and Security Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Stan Crosley?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

I'm here.

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

Hi, Stan. Adrienne Ficchi? Bakul Patel? Cora Tung Han?

Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission

Here.

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

Hi, Cora. David Kotz? David McCallie? Gayle Harrell? Gil Kuperman?

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital

Present.

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

Hi, Gil.

Gilad J. Kuperman, MD, PhD, FACMI – Director Interoperability Informatics – New York Presbyterian Hospital

Hello.

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

John Wilbanks? Kitt Winter?

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

I'm here. This is Kitt.

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

Hi, Kitt.

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration

Hi.

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

Kristen Anderson?

Kristen Anderson, JD, MPP – Staff Attorney, Division of Privacy & Identity Protection – Federal Trade Commission

Here.

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

Hi, Kristen.

Kristen Anderson, JD, MPP – Staff Attorney, Division of Privacy & Identity Protection – Federal Trade Commission

Hi.

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

Linda Kloss?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Here.

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

Linda Sanches? Manuj Lal? Micky Tripathi?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Here.

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

Hi, Micky. Sarah Carr?

Mary Kelleher-Crabtree, MS – Health Science Policy Analyst – National Institutes of Health

Hi, this is Mary Kelleher I'm attending in Sarah's place today.

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

Thank you.

Mary Kelleher-Crabtree, MS – Health Science Policy Analyst – National Institutes of Health

Thank you.

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

Stephania Griffin? And Taha Kass-Hout? And from ONC do we have Lucia Savage?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes, I'm here, thank you.

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

Hi, Lucia. Kathryn Marchesini and Helen Canton-Peters?

Kathryn Marchesini, JD – Acting Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Here.

Helen Canton-Peters, MSN, RN – Office of Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Here.

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

And do we have other folks from OCR on the line as well?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Yeah, hi, this is Christina Heide, Iliana Peters and Deven McGraw.

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

Thank you. Okay with that I'll turn it over to you Stan.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Great, thanks so much and welcome all and hope you all had a good summer it went quick I know that and I'm sure everybody feels the same. We're here to talk about a topic that's actually a little more specific than what we've been discussing and it is really access by patients and the fees to provide electronic copies of PHI and we're going to try and provide some guidance to our friends at the Office for Civil Rights.

We'll go through the background, we'll go through the access rule, the HITECH changes that made this electronic and then some of the state law issues around this and then get right to the specific questions that we're being asked and then we received testimony from a number of organizations and I'll go through the summary of that and then from there we'll need to develop a...at least we hope to develop some type of a straw proposal. Could you go to the next screen, please?

Where we are right now, we have accepted the testimony, we had a conversation earlier trying to understand the issues, we've gathered some background information, put that together in a PowerPoint presentation as well as some other materials and then issued key questions to entities that we thought we would be relevant to provide testimony and then receive testimony back and now having this conversation where we hope to develop some straw recommendations based on the discussion and then on the 28th next week we'd like to continue and make sure that we kind of finalize things and then develop recommendations that we would then submit. Next slide, please.

So, if there are any questions on the scope of the agenda, I should have asked that? Okay, so let's proceed. The purpose of this meeting is in fact to provide access guidance requested from the President's Precision Medicine Initiative. It requires HHS, Office for Civil Rights and the ONC to collaborate to address barriers as you all know. And OCR is to develop initial guidance materials to educate the public and healthcare providers about the access rights. Next slide.

The background of this from a legislative perspective or regulatory perspective, §164.524, gives individuals the right to access their health information regardless of the format in that in the original rule the covered entities may charge a reasonable cost-based fee for providing copies of health information to individuals.

And then for paper records customarily the fees are charged on a per page basis. State laws come into play setting limits on maximum charges that can be made and so there is interaction between both the federal regulation and the state laws with the state laws putting a limit on what could be charged. Next slide, please.

In 2013 the Omnibus Rule made amendments, as required by the HITECH Act, and it gives individuals, you know, it reiterated that right but also now gave individuals the right to request the health information in the form and format they wanted as long as that format is readily producible by the covered entity and correspondingly then we had issues that arose with fees for electronic copies can not include cost associated with searching for or retrieving the requested information. And as you'll see in the testimony, you know, this is the...the interaction of these two points creates some issues for covered entities as well as for the charges being offered.

The next slide, other changes made by the 2013 Omnibus Rule, individuals must be able to request an electronic copy of their health information and no access provider admin systems needs to be provided that applies only to information present at the time the request is fulfilled and they can reject it if the use of the media introduces an unacceptable level of risk and we've actually talked about that a little bit in our last working group on big data topics. And then an individual can direct a covered entity to transmit directly to an individual's designee or a third-party. Okay. Next slide. Then we'll have a couple more slides here for background.

State law fee, state laws on fees for access to medical records set maximum copying fees range from \$40.00 with some states allowing maximum fees of \$180.00 for copying 100 pages or more. And just a sample state law issues, Kentucky allows each individual to obtain one copy of their medical record free of charge, Michigan allows doctors and hospitals to charge \$1.08 per page and then down from there as you can see. So, we just wanted to provide some input and some background on the types of fees that the individuals would be facing and are facing when they request electronic copies. Next slide, please.

But and I said electronic I meant copies because few states have actually addressed the fees for access to electronic health records and those that do allow fees basically as a translation of those charged per paper record, so on a per page paper record basis.

So, Illinois for example allows doctors and hospitals to charge 50% of the paper-based per page fee for electronic records. So, if there, you know, if they're paper-based fees would have been \$40.00 then their electronic record charge can be \$15.00. The electronic per page charge includes the cost of each CD ROM, DVD or other storage media.

Ohio does not distinguish between paper and electronic records and allows providers to charge the same per page fee for both. Okay, next slide.

So, preemption, in general, under HIPAA, state laws that are less protected with patient's privacy than HHS are preempted but The Office for Civil Rights is now asking and seeking input on fees in electronic environments so the states can follow suite and ensure the patient's privacy or access rights are protected in the electronic environment. So, seeking direct guidance on how fees relate to this.

So, I think that our next...the last slide on the background, the next one, yeah, fees charged to provide electronic access to PHI must be based on a covered entities labor costs incurred in responding to the request, but, and this is the unknown, but it can include costs associated with searching for or retrieving the requested information, it may include skilled technical staff time spent to create and copy the electronic file. So, the labor charges incurred in doing these things. Next slide.

Okay, so that's right...so that's the end, before we get into the specific questions is there any question on the background, the regulatory background, the interaction between state and federal law? Okay, great.

So, here's what we're really trying to get to. So, we developed key questions for stakeholders with input from OCR and helping to see if we could get some stakeholder input and some testimony on these questions.

So, the first question is an electronic file size an appropriate proxy for “pages” in setting fees for electronic access or is it simply a substitute for a per-page proxy? And so if the file size is appropriate, how should cost be calculated and if not what is a better proxy for calculating labor costs for electronic access? Next question. Next slide, please, there we go.

Connection of patient access right to view, download or transmit requirement of Meaningful Use and so should the producible form and format of the electronic copy of the individual’s request affect how the individual is charged?

For example if they download an electronic copy under a portable thumb drive versus using the download or transmit capabilities of certified EHR technology or by e-mail all of which may in fact, you know, be easier or more difficult depending on the system. The issue may also arise when an individual uses personal health records or mobile health devices. Okay, next question.

If due to interoperability issues between an EHR where the requested information is maintained and the software used to create the copy for the individual the business associate must download the file from the EHR and subsequently upload it to the business associate’s software before generating an electronic copy. Should labor costs associated with this process be charged to the individual? So, very specific request and if so how are they calculated? Right, so interoperability issues.

If the information is located in several different EHRs should labor costs be associated with this process as well? So, you know, the burden issue on the covered entities and how that should be reflected in the cost. And then the next slide, please.

And then similarly, if information from an EHR has to be printed on paper and then scanned and uploaded should the individual be charged? If so, how should that be calculated? Next question.

Have no fear we’re going to come back and summarize with input. And would you answer anything differently if the copy of the data from the designated record set were being transmitted to a non-HIPAA covered business associate, such as a PHR vendor compared to another HIPAA covered entity or that organization’s business associate? So, getting to the issue of does the complexity change, would your cost analysis differ with this as your fact scenario.

So, let me pause there and begin...what we tried to do here in the slide deck is give the background, the regulatory background, the key issues that we’re trying to assess, so the charges, you know, that the institutions can provide to individuals and then how that should be set up and then the five key questions that we thought kind of addressed the basic issues and that’s what we were hoping to get for input from the stakeholders.

The next slide kind of breaks it down as to who we solicited input from and you can see, I’ve actually got to pull up my own slide and blow it up, because my eyes are that bad, we asked the providers, the EHR vendors and the patient groups for input and specifically, you know, list the entities that we’ve requested input from and then the testimony that was received or if not, you know, it was, you know, why was it not...did they not provide testimony.

We had a very tight deadline, a very tight turnaround and so it’s very fair that some entities may not have had enough time to respond and we greatly appreciate those who kind of responded very quickly to us and then some just said, you know, this isn’t really, you know, our issue as much as that of our customers and so we would allow them to respond rather than us as an organization.

So, those are the entities, the organizations we targeted and we got very good responses and then the staff was good enough to put together a summary of these stakeholder responses now and so we can go into this next page.

And I'll cover these questions and we can look at the summary then we can see if there are any questions you have around this because at the end we're going to try and, you know, draw out some...what we think are some straw recommendations that we want to try and make. So, if you go to the next slide, please.

So, here is the summary of the responses and I read through the questions intentionally fairly quickly because, you know, we're repeating here with the responses. So, the first question we had is an electronic file size an appropriate proxy for the page fees, charging fees that we currently have or is it, you know, just a per page proxy not a good proxy for fees?

The providers that we heard from generally said that file size should not be used as a proxy because there's a lot of things that affect file size whether it's images or other types of things that could vastly inflate the size but the costs to reproduce the EHRs should include labor costs for labor expended including segmenting sensitive information which is where they look at the request and they have to segment certain things that aren't permitted to be disclosed or that they wouldn't want to be disclosed then per page may still be a viable option.

EHR vendor summary, the EHR vendors believe that, again, also that file size should not be used, there are many factors of a file size, the same types of responses we got, but they suggested perhaps a virtual page or flat fee based on, you know, the transaction per record or a one-time fee for the storage media.

And then patient fees, you know, patient summaries were really, you know, lining up as, well we really don't believe fees should be charged unless it's a significant burden on staff time. So, they look at this as being a fairly seamless, you know, transition that if it's electronic and available it should be fairly straightforward and a simple thing to provide to patients and so it sort, you know, begs the question in their mind that fees shouldn't be charged.

Are there any questions about this first response and what we got? And then we'll get into a little more in question three and four and five, and then we have a table at the end compiling these things. So, any questions about question one or any thoughts in general about the responses we received?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Stan, this is Linda Kloss.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yes, Linda?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

And I think it's important through this whole discussion to really be clear that we're talking about fees charged to patients or designees...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

For access, because there are a lot of requests for access and while organizations may follow a standard procedure, you know, in fact their approach to charging maybe somewhat different and so I think we need to really be clear.

You know I know that there are some providers who have taken the position, as reflected on this slide, no fees charged for patients but that doesn't mean that there doesn't need to be a fee structure for other requesters. So, I think we just need to really nail that scope issue.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yes, I think that's exactly right and there has been some discussion around that very point that a lot of these entities will charge fees for precisely that...other than the patient who are requesting or for purposes other than the patient access and so I think that's a relevant consideration. And others on what we've discussed so far, this first question on the page?

Stephanie Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Hi, this is Stephanie Griffin from VA and I would kind of agree with the providers summary. We've been charging for electronic copies on CD or thumb drives for years and we never charge it as a proxy for pages. We charge what we call actual cost of reproduction so there is a labor charge and then there's a media charge, so whatever the CD costs us or the thumb drive costs us if we're the ones supplying the media. If the patient wants to supply the media, you know, there are some caveats to that, we don't always allow that, but we don't do a proxy for pages it's labor and cost of the actual media.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Hey, Stephanie, this is Lucia, are you free to tell us how you calculate the labor?

Stephanie Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

We do, it is complicated, it's probably more complicated than it should be, but it's actually how our regulations kind of have always done labor, because, you know, if you're a federal agency you've had to calculate labor for FOIA requests for decades and so it's a very similar calculation. It's actually off of salary, per hourly wage, plus 16% because you've got to throw...the government feels you've got to throw the benefit costs into that of what that person costs, so there is a 16% for the benefits on top of their hourly wage and then we calculate how many hours or fractions of an hour it takes to make and produce the records. But it...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Just a follow-up question Stephanie is do you have like a standard amount you expect it to cost in terms of the amount of hours or do you literally have like your people come develop and tally it and it's specific to each request the amount of hours?

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

It is specific to each request.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Now, you know, we have 150 facilities now a facility...we give them discretion, if a facility wants to figure out that it normally takes an hour and that unless it goes to 2 hours that's what they're going to charge is an hour we don't have anything in policy that would prevent that.

We do have though a minimum, so if your fee does not equate to \$25.00 we waive it because it costs us more to process a fee that's under \$25.00 than it is...so if the fee is \$10.00 for some reason, so maybe it took us 15 minutes, whatever, we won't process that fee we'll waive it because it costs us...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

More than \$15.00 to process a \$15.00 fee and now that's not for everybody, don't get me wrong, that's because of what the federal government has to do. We have to process all of our money a very specific way, it goes to the Department of Treasury. So, that would not certainly be for everybody, but I would think most organizations would do a cost analysis of how much does it cost you to process a fee and if the fee is less than that amount you would not process the fee because you're actually losing money in processing the fee. VA has done that and our limit is \$25.00.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thank you, Stephania that was helpful.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Excellent, any other comments?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

This is Micky, just one...I just have one question for Stephania, so, I mean, in general it seems like the principle behind this, the ability to charge under HIPAA was just related to allowing providers to charge the marginal cost of providing that record and I would think that as we move to the electronic world that this cost is moving very close to zero in terms of, you know, any of the...I mean, the bits and bytes, now granted there is a labor cost in there but I would think that that's getting pretty small as well.

And I was just wondering what do you see as, you know, sort of the main drivers of, you know, a request that takes very little time versus a request that takes a long time? You know what would take a long time if you're just generating a summary from an electronic medical record?

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Well, if you're just generating a summary it's not, it's going to...for example, within VA if you want a health summary we have...I don't know what most people do, we actually have a software package that sits on top of our electronic record for our release of information department that allows them to process requests for records. Again, today it's not...I'm talking not where you're doing it through Direct or anything, I'm talking where someone wants a paper copy...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Sure.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Or they want an electronic copy on CD, thumb drive, so they come through our release of information department. Well they have a software program that sits on top of the medical record and allows them to easily enter the request, because you have to build...you know kind of things for productivity turnaround time, I mean, we have, you know, requirements for turnaround times of process and requests, it also lets you then track it if the person calls in later for information.

So they have a whole system that sits on the medical record and it lets them put in the request, it lets them pull the record and if a health summary is what they want they can run it as a health summary, and then it lets them create cover letters, you know, so you...I mean, you normally don't just send someone...you send a cover letter, lets them create the cover letter and so they build everything.

And you're correct, to do all of that, the whole process 10 minutes.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Right.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

You know literally 10 minutes, because it's a...it's a few keystrokes.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yeah, right.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

You know 10 minutes to do that. So, you're correct. In that case VA almost would never charge because we don't ever get to our limit of minimum amount for which we're going to charge. We're not going to charge for that.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yeah.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

So, you're talking 10 minutes, it's nothing. Now if they want some...let's say they don't want a health summary but they want everything, they want their entire electronic record including images that could take you hours, you know, that could take...to pull...because it's not the record itself that would take a while it's the images...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Right.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

That would take a while and so...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

So, you're pulling that in from other systems and having to put all that on a single...

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Exactly.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

And you're also maybe trying to compress them.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

You're trying to...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Right.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

So, to your point a health summary you're correct, you're almost...you're talking minutes, 10 minutes or so to do that and for us it's the whole process entering the request, pulling it, the cover letter, I mean, it's not long. But if they wanted their entire electronic record including images now you're getting into some time.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Yes, okay, thank you.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

This is Linda Kloss again and I would say that, you know, in terms of hourly rates plus fully loaded costs for employees, you know, most healthcare organizations also, you know, maintain a service, you know, they staff an area where people can come and visit with someone if they, you know, don't know what format they want it in or can handle it in. So, you know, that maybe something that gets spread across all requests and as you look at this as a...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

You know Linda, this is Lucia, that's really helpful but definitely one of the things we on the staff side observed as we were compiling information is that both of you are correct, people do have a business model providing this as a service for a fee to covered entities and theoretically the cost should be falling as things become automated or automatable and I think that's kind of the driver behind the whole dialogue which is, you know, what in the environment has changed that could help inform OCR as it writes this additional guidance.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Agree, I think though it is important to know we're still in transition often.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yes, yes, okay, any other questions? We'll go to Q2 and then we'll have an opportunity to come back and further discuss these. Any other thoughts on either the EHR vendor summary or the patient summary? Okay, let's go to Q2.

Should the producible form and format of the electronic copy the individual requests affect how the individual is charged?

And we got a little bit into this already and I suspect we'll start crossing over questions, but the provider's summary basically was that if it's something that's not easily accessible or easy to provide there should be...somehow there should be an additional charge that can be built in and then some also just translated it directly to labor cost to do so which is I think what we just heard from Stephania.

For the EHR vendor summary, deviation from the defined standard format was what we heard should impose some additional cost. Others stated that if it requires view, download, transmit that the VDT requires a C-CDA and if what is requested is more than that there should be additional charges on top of it.

And then the patient summary is, again, the whole point of the regulation was that we should be able to request form and format and so there shouldn't be a disincentive to do so.

So, any thoughts or, you know, ideas around this slide?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Stan, this is Lucia, I just have a follow-up question about the patient summary, did any of the patient commenters comment about the difference between the reimbursable cost of the medium like we talked about before the cost of a thumb drive or the cost of a CD ROM versus copies of the electronic records or did we not get that level of detail?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

I don't remember seeing...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

I can't remember.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yeah, I don't remember seeing a differentiation.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay. We'll look for that and make sure that if there is a comment about that it gets floated back to committee next week.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay, yeah.

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – Office of the National Coordinator for Health Information Technology

This is...sorry, this Devi from ONC, there was not a differentiation as an FYI. I'm just looking through the summaries and there was not.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay.

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – Office of the National Coordinator for Health Information Technology

And if there is I will note it but I don't think there is.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay, thanks.

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – Office of the National Coordinator for Health Information Technology

Thanks.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

And we...so let's go to the next question, because again I think this is going to roll together a little bit. If due to interoperability issues between an EHR and the software used to create the copy and the business associate would download the file and then the person would upload it to the business associate's software for generating an electronic copy for an individual should labor costs associated with this process be charged to the individual?

And the provider summary said, yes, they should allow BAs to charge labor fees.

And the EHR vendor would allow charges on a flat fee or per transaction basis.

And then the patient summary, labor costs are not reasonable because it is a business decision to maintain differing non-interoperable systems. So, the idea of who is in the best position to, you know, take the fees and respect that fact that it should be, you know, a...in the system.

So, any thoughts on this summary? To some extent I think we're probably getting to the difference between how a patient may perceive a system and what they can control versus what they cannot control and now we're getting into some things that are beyond the patient's control and I think what we were hearing is they don't want to be charged for those things that are outside of their ability to control. Other thoughts? The workgroup is ruminating deeply on this issue. Let's go to the next question. I think we can start some additional questions.

If information from an EHR has to be printed on paper and then scanned and uploaded to a different software program used to create and/or send the copy should the individual be charged and how should cost be calculated?

And so, again, the providers kind of stuck in this world are saying that we would have to be able to charge costs if we're required to do this.

And the EHR vendors were suggesting that while they should be allowable and one responded that, you know, charging such fees is debatable.

I think that, again, to the patient point this is kind of getting to if the EHR is then implemented and perhaps, you know, five years from now we're at a more seamless circumstance these aren't reasonable charges but, you know, the question is, you know, if the provider is in this world and they're being asked these questions and being asked for it can they charge, should they be allowed to charge these fees? And I think we get a fairly sharp contrast here between providers and what patients feel.

Any thoughts from the committee on this or the workgroup on this? I think this is a pretty significant question.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

This is Stephania Griffin from VA, so is the...is anyone contending that you would be legally prohibited from charging? Because the question is just very odd to me. I mean, I'm trying to understand are you doing the scanning and uploading at the request of the patient or are you doing it to meet some requirement under Meaningful Use?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Or are you not able to provide it in electronic form for some reason?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

So, Stan, you want to take a stab at answering this? I mean, this is Lucia, all the questions are in the context of a patient request under the rule §164.524 so it's not for another programmatic purpose, but in that context what we heard is that sometimes people...the way they're electronic health records keeps the data in order to turn it into something comprehensible by a patient in response to an access request this process is undertaken.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right and I think that was...

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

So...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

The last two have that just different versions of the same problem.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

From our perspective in VA the way we interpret the HIPAA Regulation it's you give it to them in the form and format if that form and format is readily available. And you certainly can always charge for copies under right of access, which is what this is still part of.

So, if VA was asked to do this by an individual, so let's say the individual...and we actually have this right now going on but not because of this but because of 504, we have people asking for things in alternative forms to deal with 504 compliance, a little different, but up to this point if you wanted us to do this we would charge you.

So, if you wanted us to...if there was no way that we could download it electronically for whatever...it didn't exist, you know, you wanted us to put it in something other than PDF and we just couldn't do that so that we would have to print it, scan it and put it in a different program we would likely charge them.

We would offer them all of their, if you will, free options because we give our patients one free copy. We would probably offer all of their free options and say "here's all your free options." And if they said "nope I don't want it that way, I want you to go through all..." and if we even had the software program they wanted it in "I want you to do it all this way." We would likely charge them for it and we would likely charge them the actual cost. We would not charge them like by page printed, we wouldn't worry about that, we would just charge them the actual cost to do it likely which would mainly probably be the labor cost and the media cost.

Again, if you get into 504 issues it's different, but in this situation we would likely charge them.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

I think that...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

And I suspect that your answer would be the same on both question three and question four if the...either your EHR wasn't interoperable with the software that the patient was requesting be used or at least be translated to or if they wanted to add something would require you to scan it and then upload it you would have the same basic response that...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Or the...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Or the alternative format.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Or the scope of the request required you to do this whereas some of the data may have been electronic and others...

Stephanie Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

But...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Non-electronic and I think it points out that it would be very difficult to set guidance here by describing the particular process because in reality all of these processes are in play.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

So we have to kind of step up to another level and describe costs for the information management processes.

Stephanie Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

I will say just anecdotally we receive in VHA over 1.2 million requests for records a year, about half of those are for veterans for copies of their own medical record so we process a lot of requests for veterans for their records. And we get sometimes some very outlandish requests but normally, the 99% of the time, when we offer them their options we'll do, we can give it to you this way, we can give it to you that way, we can do this, we can do that, normally they are satisfied with another option. Often they just didn't realize what their options were and they were kind of making a request not really understanding what was possible. So, I don't know if that's very helpful but we don't get too many outlandish requests.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yeah.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Stan, this is Lucia, can I ask Linda a follow-up question?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Absolutely.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

So, Linda, I wanted to explore this idea, you know, the guidance on particular fact patterns is hard because the process any particular organization and it's vendors uses varies so much, but is there...do you think it would be helpful as we're trying to sort of make sure people are, you know, doing their best to comply with the spirit of this rule, which is patients should be able to get to their data pretty easily, to sort of talk about, you know, I worry about the situation where you can downstream the costs of, you know, a gold-plated Porsche Roadster business associate agreement, business associate who, you know, does white glove service on this but then you off load all those costs onto the individual if you can downstream the costs of the covered entity.

So, is there a value in fact patterns that are about, you know, clarifying the difference between search and retrieval that you're not allowed to charge for according to the summary we gave you before versus copying and that kind of thing so that people understand what...in a relationship between the covered entity and the vendor who is helping them with this document responsibility what they can and can't charge for, is that helpful?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Well, you know, I'm not sure I can say absolutely yes or no. It seems to me that what could be helpful is to describe the categories of costs that could be covered, you know, the hourly labor directly applicable to satisfying the intent of a request, you know, with the labor costs with, you know, reasonable overhead or something, but I think it's kind of hard to tease apart the pieces of the process, you know, retrieval, you know, may, you know, maybe fulfilling the request is a combination of an electronic retrieval process, a paper retrieval process, requesting information from, you know, other covered entities in a network, you know, it could be a variety of steps and processes.

So, I think it just is tough to get too granular. It might be easier just to say what categories of reasonable labor costs would be covered and have them perhaps specify that they are directly applicable to satisfying that request for that access rather than, you know, other kinds of overhead costs. I'd just throw that out.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

That's helpful, anyone else on the workgroup want to comment on my question? This is Lucia.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Hi, Lucia, it's Christina, I would. I do think it would be helpful if we can get some guidance on or some thoughts on where the line should be drawn between search and retrieval, identifying the records, finding the records that are the subject of the request versus just the action of creating the copy.

And, I mean, I think from our perspective in terms of getting to a point where we have some guidance that is fairly broadly applicable some information in response to that question would be very helpful.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

So are you getting...are you kind of getting to the issue of, you know, is it related more to the providers environment versus provided to the type of request from a patient? And so that...whether it has to be searched or retrieved from remote sources or something is more about the environment than the request?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

So, I'm not sure of the question but, you know, whether the information is held in a remote area and that to me is search and retrieval and if that cost associated with bringing that information forward are not permitted.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

But why would they not be if that was integral to it?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Because we do not allow for search and retrieval.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

And we haven't. And the Omnibus Rule stated that this continues to apply for electronic records as well.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

What we did say in the preamble was that you can charge for or a lot...a portion of the fee for the skilled technical labor costs for essentially creating the copy and I think the example was burning the CD. So, we need to draw some line between search and retrieval and creating the copy.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

I see.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

And it is not an easy question.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay, so I see what you're saying, okay.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Yeah, I think it's an important question that we would love some recommendations on.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Anybody care to comment on the question or provide any elucidation on the conversation so far about how much of that is search or retrieval or where lines might be able to be drawn? We can certainly come back and refine that to see if any of the responses included that distinguishing point. I don't recall.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

So, this is Micky, I just want to make sure I understand what search and retrieval means. What Stephania was describing earlier with respect to having to pull together all the images if the patient requests everything that the VA has on them would that count as search and retrieval?

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

I think that's a harder question to answer and it raises some of the questions that have come up is, you know, once you have identified the information, that is the subject of the access request, what else can you charge for in terms of getting that information onto a CD or in some other format that would get the information to the individual. So, I think that's a tougher question and is one of the things that we're looking for some feedback on.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

This is Stephania Griffin from VA and not that we would necessarily want to adopt it but certainly it could kind of inform, there are kind of very good definitions of search and retrieval in FOIA and how FOIA looks at those terms and what they mean and again I don't know that you would necessarily want to adopt a similar framework but at least you can see what legally is out there to how these terms are currently defined by other statutes.

And, you know, they break down search and retrieval is different than processing and so when you look back at FOIA search and retrieval is kind of exactly what it says, it is searching for the records trying to locate them and then getting them into your hands which is different from what they...then the processing of once you have them.

Again, I don't know that we would use those same definitions but you can use it to kind of inform what's out there in other contexts.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

There is another step in that, you know, identifying the right information that aligns with the request. So, you know, the search isn't...I mean it's a...takes focus and attention to make sure that we've accessed the match person index, do we have the right person, where are all the parts that meet the access.

So, I think it is in fact a process and one of the positions we probably should be taking is an understanding that it is a process and a process that we want to see streamlined over time so costs are reduced.

And whatever we come out with rather than piecing and parceling this out the way we've so often long done building this cost structure around this is to try to find a way to drive costs down, because I think that's in the spirit of what we're trying to do.

You know I would...if it were reasonable and possible, you know, I would agree with the patient not being charged, but it's still a laborious process in many organizations, but I think we should be setting the bar to drive these costs down to as close to zero as possible. But I don't think the way to do that is to separate pieces of the process.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Michelle, we had talked earlier about letting the public know that they could start queuing and if we a lot of public comment we would provide more time for that toward the end of our call or allocate more time for that given the nature of this issue. So, I think that's worth referencing now in case we get some people in the queue.

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

Sure, Lonnie or Caitlin do you want to open up the lines and then we can just go back to the discussion.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay.

Public Comment

Lonnie Moore – Meetings Coordinator – Altarum Institute

Sure. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay, I didn't mean to curtail anything, if we could go back now and add some conversation and see if we had some queuing given the nature of the topic we wanted to give the public adequate time to provide input.

So, I think this has been a good conversation and we've gotten some good notes on both question three and question four in particular. Let's look at question five briefly and then we can come back and look at the overall table compiled answers and try and get to some key issues perhaps.

So, question five was, would you answer anything differently if the copy of the data from a designated record set were being transmitted to a non-HIPAA covered business associate such as a PHR vendor compared to another HIPAA covered entity or that organization's business associate?

And the responses that we got...can we go to slide I think 21 versus this is 15, maybe it's just my computer but I don't see it, oh, there it is.

In the provider's summary was that most did not think there would be a difference as long as it was a HIPAA compliant request. One provider also noted that the provider should not be responsible for any charges if the patient is paying for the third-party service.

The EHR vendors said that most stakeholders said there would not be a difference, while one said there would be, again, if there was a competitive risk.

And the patient summary, the patients basically took the position that, you know, we're again not asking for any difference in what we're requesting so what happens on the back end really shouldn't be a patient issue.

So, thoughts or conversations around this? And there is certainly...you can see a thread coming out certainly from the different perspectives. Any thoughts on question five?

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

This is Micky it seems hard to redefine the justification for charging any more as long as the delivery format is the same.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

I agree.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Micky this is...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yeah.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

So, I have a follow-up question about that, I think the practice today is for example if a person asks directly then the access to the patient rules of the organization apply but if the person hires a lawyer and the lawyers asks then charges are different. Is that what you were eluding to when we started this conversation Linda? That people have different ways of charging depending on who the immediate asker is not on whose behalf they're asking?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Correct.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

So, do you think this is sort of in the same vein or coming from the same sort of organizational thinking?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Yes.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Okay.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

It's a longstanding issue.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Well that...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

And point of contention no question.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

I'm trying to describe it as neutrally as I can.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

I assume this is more of the PHR vendor scenario but that does make sense what you're suggesting

Lucia. Yes.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

So, this is Christina Heide if I could just ask a question about the question, which I'm now a bit confused on. Was the intent for this question to be an access disclosure? In other words the individual directing the copy...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

They would otherwise be entitled to, to a third-party or is this just a permissible disclosure to a third-party outside of the access context?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

It was the first.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

This was intended just an access Christina so like an individual asks for their data to be sent, transmitted if you will to their PHR.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

To a third-party, yeah.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Okay, thanks.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

And I was curious if we would get people suggesting that there would be a legal review necessary or some type of legal review if it wasn't straightforward on the designation where it was getting sent to a non-HIPAA covered entity would there have to be some type of an internal review process that would be captured but...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Well there...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

We...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

I think one of the...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

So...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

One of the commenters noted that there may be a security issue that certainly the patient needs to be apprised of.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Right.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights
Right.

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative
Yeah, because...this is Micky and, you know, Lucia or anyone else correct me if I'm wrong, but it's my understanding under HIPAA that if the patient designates it that's it. I mean, maybe you have an issue around security and making sure they understand, the patient understands the security, but at that point there is no definite...the notion of HIPAA compliance doesn't matter anymore the patient has designated it.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Well to break that down just a little bit...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
That's right in an...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Micky...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
I'm sorry, Lucia.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Go ahead Stan.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP
I was just going to say, you know, that's exactly right, you know, in a clearly understanding and fully informed universe, but what happens with providers is that they have, you know, a set of criteria that they can comply with and then anything that's outside of that they would then either seek council or others and depending on the sophistication of the entity, you know, smaller businesses want to ask, you know, send something to someone that's designated, you know, they may incur additional costs. You're right technically, I mean, you're right under the regulation it's not a problem it's a reticent risk issue.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology
Hi, this is...

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration
The other thing to...go ahead.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Stan this is Lucia just to clarify for Micky's question, there is...if the requesting patient is presenting a media on which the data is to be loaded and there is concern about the security of that media like the requesting patient presents a thumb drive and the discloser doesn't know that the thumb drive doesn't come with viruses and all kinds of bad stuff on it there can be some legitimate security concerns raised by the discloser but the discloser isn't free to refuse to disclose because they think where it's going is an unsafe place.

That doesn't mean that it might not be a good idea to warn the individual but they can't say "well, you're going to post it on a billboard at Times Square" that's my favorite example "that's insecure" it's outside of the discloser's hands what the patient does with it when they pick that third-party.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

So, this is...

Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative

Right, because...go ahead, I'm sorry.

Stephania Griffin, JD, RHIA, CIPP, CIPP/G – Director, Information Access & Privacy Office – Veterans Health Administration

Yes, this is Stephania Griffin and yes what the individual was just saying completely agree with. There was one point of clarity though I wanted to provide from a prior statement. And the FHA Workgroup on Direct has put out guidance on this and that's when a patient wants a covered entity to send their record on their behalf to a third-party, yes under HIPAA you're good as long as they meet the regulatory requirement, which is they're supposed to give you a written request designating who the third-party is and where it's supposed to go. And HHS, OCR has already addressed some of the security concerns of that.

But what you do have to remember is providers have other confidentiality laws they might have to comply with and HIPAA is very clear the more stringent law wins. So, while it's a type of right of access under HIPAA it's not a type of right of access under 42 CFR Part 2 or the Privacy Act for those of us who are federal agencies or maybe under some other state confidentiality laws that provider has to also comply with.

So, you do have to keep that in mind that you can't just look at the HIPAA Regulation and say "there's never an issue." There may be depending upon what other confidentiality laws apply to that information and that request.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay, great. Any other thoughts? Okay. So let's go to the table with compiled responses and kind of get a general feel of where we are on each of the issues and the perspectives because I found this table very helpful, you know, should file size be a proxy for page fees and generally the answer was "no this isn't going to work really well for a variety of reasons."

About, you know, would form and format affect the requested charge and again you're seeing the response if it's standard format, you know, it likely should be easy but if it's not standard format there will be, you know, labor charges involved.

And then again for question three, you know, there should be the ability to charge fees and the patient perspective of, you know, this is kind of out beyond our issue, this is an internal system issue where their own systems can't communicate with one another patients shouldn't have to pay that whereas in four if it was a patient generated request that was outside the normal format then costs should be charged potentially.

And then is there a difference with a transmission to a non-HIPAA covered entity? And here I think there may be some misunderstanding potentially in the responders or at least they were reading in different issues into the question but they appeared to say "no that should not be an impact on the fees."

So, any thoughts on this table as it sits and kind of...you know to me it seems like the patient perspective is that if we requested, you know, a format that's not standard we can understand there may be a charge, we understand that everything else though this should be a seamless universe that we're working in and so the charges should be negligible.

I think we've heard some great comments from Stephania at the VA about the practical applications of how this works and what might work and what FOIA also does. So, any thoughts on where we are here at the moment when we start to try and find some threads or some guidance that we can provide? Lucia did you have any thoughts on the overall chart?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

No, I mean, I think the chart is good. I think that what we should...what we need to figure out how to do, that's on us Stan, is to help get to the core of Christina's question since she at OCR, and OCR really have the burden here, which is, you know, where does search and retrieval and copying begin...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

In our new technological environment. So we will see what we can do to elicit either information for the workgroup or figure out a way to tee that up for part of the discussion.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yeah and I think there is...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

And maybe some strawmen or whatever but we only have next week and I think that's really a super important fact pattern if we can figure out what to say...what people might say about it. There doesn't have to be consensus that's why we have OCR on the line is so they can hear you guys ruminate.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yeah, yeah and, you know, I do think that there is, you know, there has been some clarity between, you know, the question three and question four that we've heard that we both got in the responses as well as what we're hearing today on the types of charges and the reason for the difference in the costs whether it's patient driven or if it's...if the VA is offering, you know, reasonable formats that would be cost free or less expensive and then be required to provide it in a format that is costly. So, I think there's some reasonability that we understand there. Okay. Any other comments from the workgroup?

You know I do think we're going to have to...we will come back with some, you know, with a couple of straw recommendations as Lucia just said around, you know, search and retrieval versus copying and labor fees and then based on those conversations we might be able to tease out a few more recommendations.

If the workgroup doesn't have questions then we can open up to the public and see if anyone is in the queue but does the workgroup have any other questions or comments, or thoughts? Okay.

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

Hearing silence Stan we did have one person queued up for public comment. I just want to make sure that he is still there.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Great.

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

We had Adam Greene.

Adam Greene, JD, MPH – Partner – Davis Wright Tremaine, LLP

Yes, I'm here, can you hear me?

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

We can.

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

Yes, we can hear you, so just a reminder to those with public comment that public comment is limited to three minutes if you could just state your first and last name and if you're with an organization that would be appreciated. Thank you, go ahead Adam.

Adam Greene, JD, MPH – Partner – Davis Wright Tremaine, LLP

Okay. Hi, I'm Adam Greene, I'm with the Law Firm Davis Wright Tremaine and I have a number of clients who have different interests in this area some are technology companies that are helping us move to a point where it is kind of one button click access for patients to be able to get their access, but I have a number of clients who are release of information companies who are working in the reality that we have today, which is that it is a very significant process currently to obtain a copy of a record whether it starts off electronically or on paper.

I actually used to be at HHS working on HIPAA and there I had a misconception that with electronic health records it was merely the press of a button, the equivalent of control P to print off a copy of the medical records, but what I've seen in practice is that it is anything but that, it is actually, in practice, often times a longer process than when the record started off on paper and this is not a process of search and retrieval but once you've identified the individual going through the relevant episodes of care pulling out those episodes, confirming that they are the right patient, because sometimes mistakes do happen, checking for any Part 2 information under the alcohol and substance abuse confidentiality rule because especially if the requester is asking that it goes to a third-party there could be significant additional requirements if any of the information does include Part 2 information, and going through and, you know, the reality is no one is going through the process of taking it from the EHR and putting it into additional software because they want to, because, just for the heck of it.

The reality is that sometimes is the most efficient way to be able to produce this documentation and the end result is that we are a long way from one press of a button to be able to create a comprehensive set of medical and billing records but rather it can take hours, it can take more time than even if the record began as paper records. Thank you.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Thank you very much.

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

We also had a public comment put into the public chat. It was from Mark Underwood at Krypton Brothers and also representing the NIST Big Data Working Group. He has two comments. I'm not sure this discussion encompasses near real-time access to EHR. In urgent care the profiles mentioned end up being after-the-fact limiting utility for patients.

His next comment is, there are proposals to charge more for exporting to a PHR versus print or PDF and he says he thinks there would be incentives for interoperability. And that again was from Mark Underwood from Krypton Brothers.

And it looks like we don't have any other public comments.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay, great, thank you. Well we are...we're at the last slide and we're looking at about 15 minutes left. I want to make sure that anybody on the workgroup or on the phone that has other questions or comments for us to consider that we're doing that as we start to think about the straw proposals that we're going to bring up and so if you have any other questions or comments please go ahead and make them now or certainly get in touch with us and let us know if there's other things we can include. So, are there any other comments from the workgroup or others on the phone?

Okay, Lucia as far as a next step then we're going to try and...I know we're meeting and we're going to try and develop some straw recommendations and get them to the Workgroup...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yes.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Prior to the end of the week.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

And we'll also...we're also going to try and dig up the actual definitions in FOIA so that we can try to...I'm sure they're voluminous, but distill them down for the workgroup and that might be part of the strawman that we end up getting out to you guys on Friday.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yes that's a good idea.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

For next Monday.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

This is Linda and would it be helpful to go back and see if we can understand where the distinction between search and retrieval and the copying expenses...where that came from, where that distinction came from?

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Well, Linda...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Yeah, I don't know if I...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Since we're doing this to help OCR gather information and that's their regulation my operating assumption is then they know where they started from.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Yeah, yeah, okay, but I'm...

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Christina that would be a fair assumption correct?

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

I may go back and look.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

Yeah, that is, it's in our published guidance, so...

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Right.

Christina Heide, JD – Senior Advisor for Health Information Privacy – Office for Civil Rights

As well as the preamble.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Right.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

I was just thinking going back to the Federal Register and seeing what was said about that.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Yeah there's actually...

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

It's in the preamble.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

A fair amount about it in the 2013 preamble for the Omnibus Rule if you want to really geek out Linda but we're trusting OCR to manage that for itself so we don't have to.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Okay. Okay. If there is nothing else then I think we can conclude just a little bit early and we'll get to work on the next steps. Thanks very much everyone and thanks for calling in.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Thank you, Stan.

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

Thanks, Stan.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

All right, thanks all.

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

Thanks, everyone. Have a great rest of the day.

Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology

Bye.

Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics & Applied Research (CLEAR) in Health Information – Drinker Biddle & Reath, LLP

Bye-bye.

W

Thanks, all, bye.

Linda Kloss, RHIA, CAE, FAHIMA – President at Kloss Strategic Advisors, Ltd.

Bye.

W

Bye-bye.

Public Comment Received During the Meeting

1. Mark Underwood: Krypton Brothers / NIST Big Data Working Group: Not sure this discussion encompasses near-real time access to EHR. In urgent care, the profiles mentioned end up being after-the-fact, limiting utility for patients. (Velocity in Big Data)
2. Mark Underwood: Krypton Brothers | NIST Big Data Working Group - There are proposals to charge more for exporting to a PHR vs. print or PDF. You'd think there would be incentives for interop.