



HIT Policy Committee Privacy & Security Workgroup Final Transcript September 28, 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 today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Stanley 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. Michele Krajewski in for Adrienne Ficchi?

Michele Krajewski, MS – Deputy Director, Health Care Security Requirements – Veterans Health Administration

I'm here.

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

Mary Kelleher for Sarah Carr?

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

Hi, I'm here, thank you.

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

Bakul Patel? Cora Tung Han? David Kotz? David McCallie?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, David. Gayle Harrell? Gil Kuperman?

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

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?

John Wilbanks – Chief Commons Officer – Sage Bionetworks
Present.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, John. Kitt Winter?

Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration
I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Kitt. Kristen Anderson? 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
Hi, Linda. Linda Sanches?

Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office of Civil Rights
Here.

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

Hi, Linda. Manuj Lal?

Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer – PatientPoint Enterprise

Here.

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

Micky Tripathi? Stephania Griffin? And Taha Kass-Hout? And from ONC do we have Kathryn Marchesini?

Kathryn Marchesini, JD – Deputy Director for Privacy Policy – 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 Devi Mehta?

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

I'm here.

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

Hi, Devi.

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

Hi.

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

Anyone else from ONC on the line? 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

Thank you and wow great group, glad you could all make it. And we have what we'll see is a fairly straightforward process today, we are kind of in the midst of providing straw recommendations to OCR with some of their...for their upcoming sub-regulatory guidance that's really our only business today. So, we'll continue this discussion and hopefully come to some type of resolution on the type of proposals that we would make and really the kind of...coming in the form of discussion points that would help inform OCR not really recommendations. Next slide.

I'll give a little background here. We are now on this process of developing the suggestions and the final discussion points in this conversation and at the conclusion of this hopefully we'll have some good discussion points for OCR. And can we go to the next slide?

So, just to kind of retrace our steps a little bit. The Office for Civil Rights has requested some input for the...it started back with the President's Precision Medicine Initiative, HHS, OCR and ONC collaborate to address barriers to prevent patients from accessing their health data. One of these barriers is that OCR should develop additional guidance to educate the public and healthcare providers about a patient's right to access his or her health information under HIPAA. Next slide.

And then the specific ask that we had is to provide input on the amount of the cost of fees that should be charged to patients with respect to these access requests that HIPAA now allows them to make and the HITECH Act made electronic.

And so we sent out a request for input from individual entities and got back responses from three sort of distinct groups and provider groups that were providing the healthcare, vendor groups those who are in support of those providers and then patient groups who are the ones of course requesting the access.

And the key questions that we had were set forth on the left-hand side, in the left-hand column there, that the Office for Civil Rights would like input on, should file size be a proxy for page, form and format would that affect the charge, could labor costs for VA to generate electronic copies for the patient and then charge if the electronic health record has to be printed, scanned and then uploaded again and then different if a copy of data was transmitted to non-HIPAA covered entity would those...would our responses be different. And so those are the summary of the questions and you can see the responses we talked through last week. Let's go to the next slide.

And so in general and just to recap our discussion and where we are right now, the question was should electronic file size be a proxy for pages in setting fees for electronic access or is it simply a substitute for per page proxy?

And the answers were, you know, pretty clear across the board there really wasn't a very good proxy, really it's more about labor charge and media charge and there may or may not be...but it wasn't a good proxy the per page versus the file size.

And then we had some comments from the VA that they use a regulatory-driven calculation and they have a set minimum amount and that minimum amount was set because if it's less than that it's actually not worth it for them to generate the invoice for the fee and so any cost under a minimum amount then is waived, again, that's very VA specific, but we had some very good input from the VA the last session. So, the next slide.

I'm going to go through these and then question two is should the producible form and format of the electronic copy the individual requests affect how the individual is charged? And we had, you know, input that suggested that it may be useful to look at the FOIA definitions for form and format, you know, should there be a differentiation cost for patients?

So, some of the conversation here started to get into the idea that we may not...if the patient is requesting a format that is a non-standard format or if the providers have a standardized format that they provide in an electronic copy and it's a common format then there may or may not be a justification of a charge and if the patient is asking for a format that's different than that which they already offer then they may be more justified in charging fees and there was that discussion.

And then there was another discussion that was about, you know, should there be differentiation of the cost for patients.

So, if you look at those first two questions just to kind of, you know, round out where we are I think that...oh, I'm sorry, the next one too, go to the next slide too.

And then question three was, if there are interoperability issues between an EHR where the information is maintained and the software that has to be used to create a copy for the individual should there be a...should labor costs associated with this process be charged to the individual? And this is where we had a sharp differentiation between the providers and the vendors, and the patients with the patients saying, you know, it's not really their fault that there was a...that there are interoperability issues and the providers and the vendors saying, this is just the reality of where things are right now and it takes a lot of effort to potentially make these copies.

So, the summary then of the first kind of questions two and three was that there really wasn't a clear consensus position with input from patient groups, input from vendor groups and input from providers generally had the patients and the PHRs on saying that, you know, those charges probably weren't legitimate and then the vendors who are BAs and the providers suggesting that, you know, fees should be allowed because of the labor costs and the copying charges.

So, then, I think we can go to the next slide, is Q4 and then we'll have some discussion. And then the final kind of twist in that was, 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 a copy should the individual be charged?

And again, the conversation was along the lines we just had as well as, you know, patient comments saying "no" and the vendors and the providers saying "yes" and the fact patterns and the categorization to charges, you know, could be very useful and this could be very fact specific.

If there was a range of hypotheticals the workgroup felt that we could perhaps give a little more guidance to OCR on the specifics of which circumstance would mean, you know, a charge would be reasonable and which circumstance it may not be, but generally fell along the lines...and again the VA provided some comment that, you know, they offer, you know, a number of...a variety of standard formats for electronic copies and if a patient wants something other than that they feel more justified then in creating a charge around that and charging for labor fees to produce it.

So the recommendations then, let me see if on the next slide if we had a summary of the Q5 too, but that's a different one. So, Q5 deals with kind of a different issue than on that specific piece and this is one where we had some discussion...this is if the designated record set were being transmitted to a non-HIPAA covered business associate, you know, would we have a different answer on any of the foregoing costs?

And we did talk about, well there are legal risks, there is certainly differentiation and laws, there are legal review implications and so question five tends to be different. So, we had question one and question five which we seemed to have some general guidance around with input on and then questions two, three and four tended to kind of flow together in general of saying, we may need more information before we can give, you know, specific input or guidance that we've created a lot of input from interesting parties. So, that's the summary of what we discussed in the last session.

We also had a conversation, let's go to the next slide, we also had a conversation about, you know, would FOIA be a good statute to look at for purposes of search and retrieval versus copying costs because under the regulation providers can charge for copying costs but they can't charge for search and retrieval and so the definition of understanding, you know, what search and retrieval was versus what copying costs and labor associated with that would be important and so this kind of sets out the direct cost in search and duplication or review from FOIA which would allow that under...FOIA and the search is defined. I think the helpful definition is to review manually by automated means agency records for the purpose of locating those records and so the search is an idea of being located.

We had public comment submitted that was along these exact same lines that is available to the workgroup as well suggesting, again, that manual search and electronic search are very similar and their attempts to locate the records, once the record is located the labor to actually produce the copy was what the significant labor is around.

So, now one more slide, so then there was the HHS regulation along the same lines as saying, you know, here is what has traditionally then...actually I think we can go to the next slide is the one I wanted to get to for conversation.

So, I think, you know, based on the previous five questions, you know, let's have a little bit of a discussion. I think we have, you know, some response on questions one and five perhaps, but a little bit more muddled on two, three and four as far as any consensus.

Are there thoughts on, even if you look at the...kind of the key of the things that we think needs some more clarity that would help us provide some input? Are there any other topics in here that you think we should include? Any further clarification we want or do you have comments on the positions we've generally received on the first five questions there?

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

Stan, this is Linda Kloss, and I had kind of the fortuitous happening that I've been at the AHIMA convention these past few days and have been having conversations on some of these concepts...

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

Great.

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

With people that I respect. One of the concepts that we may want to include here is a question about where do the functions of the quality check and the HIPAA compliance check go, are they part of search and retrieval or are they part of the copy portion?

It seems that from the conversations I've had with people who manage these functions that that's the value add part.

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

Yeah.

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

And it is the part that done well ensures that the correct information is getting to the patients in all of the information that's being requested. So, I think we should perhaps add a question about, you know, does that quality check and HIPAA compliance check belong in search and retrieval or is it the copy end of the process. It seems like we've got a step in this imagined process that's missing in the way it's being described currently.

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

So, maybe a talking point there, under how to define search and retrieval another sub-bullet of clarification around where quality check and HIPAA compliance confirmation goes.

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

Yes.

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

We can also put...frankly, you can put state law and, you know, other federal law in that HIPAA compliance check as well.

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

Yes. So, if you have to review the record and exclude some of the sensitive information that's required by state law, you know, is that search and retrieval or is it a decision that's made the copy end of the process.

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

Yeah.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

The...

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

So, just those first two.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Stanley?

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

Yes?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David McCallie and I apologize...

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

Yes, go ahead David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

That I missed the first meeting on this topic. But remind me what the use case is in terms of who is requesting the download, is this any release of information or it's just always the patient and it's...

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

Yeah, this is...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Their own effort?

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

Yeah, this is the patient request that could be designated sending it to a third-party.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Okay, but it's a release to yourself rather than a release to a...oh, wait, you said, it could be third-party but it's...

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

It could, yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...release.

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

So, it's a patient initiated.

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

Yeah, patient initiated request that...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So, what degree of HIPAA compliance needs to be ascertained in that use case? I mean, it's the patients record what are they going to restrict?

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

Right, the question may be from Linda there on either it's a security check or we certainly had a conversation around other federal parts of, you know, psychological notes or psychoanalytical notes, or, you know, other Part 2 sensitive topics or if it's a state law restriction. But as far as HIPAA compliance the disclosure piece would be pretty straightforward. There may be other HIPAA issues I guess on security or, you know, transferring among entities.

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

Well and conforming to whatever the authorization specifies.

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

Sure, sure, yeah as far as disclosure to another entity or the form or format right?

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

This is Christina Heide with OCR; can I ask a little bit more about what you mean by state laws that are more restrictive?

I mean, if we're talking about state laws that would provide less information to the individual or the individual's designee in this case which we consider still to be an access disclosure, if there's a conflict there we would pre-empt those laws.

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

So, this is Stephania Griffin, what you just said doesn't quite...I'm not sure makes sense to me. What y'all have always said is that when it comes to making a disclosure that more stringent law must be adhered to and the example I'll give is not a state law but is a federal law, what they were talking about 42 CFR Part 2 which or 38 USC 7332 which would require an authorization from the individual in most situations in which you're making a disclosure to a third-party and while HIPAA Privacy Rule does consider it a right of access disclosure for the patient to designate a third-party to whom a covered entity should send their record those other laws consider that a disclosure.

For example, 38 USC 7332 doesn't have a right of access provision. So, if a patient says disclose my record to "x" third-party it's a disclosure and 9 times out of 10 is going to require an authorization. And so even though HIPAA...

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

Right.

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

Privacy Rule considers it a right of access where they still have to make a written request, designate the individual and designate where you want to send it that's not an authorization.

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

Right but...

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

So we have always understood the rule to say, the HIPAA Privacy Rule Regulation on that, which is less stringent, doesn't trump 7332 and override it you still have to comply with 7332 because it's more stringent.

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

So, with respect to the other federal laws like Part 2 presumably when the individual is providing what's required under HIPAA in terms of the written request they'd also be providing the Part 2 consent to have that information go to their designated third-party. But with respect to state law...

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

And the same thing under state law.

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

Yeah, with respect to...

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

But...

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

State law, however, there's a special...in terms of more stringent, there's a provision that applies specifically with respect to access and amendment, and a more stringent state law is one that provides greater rights of access. And so it's different from the disclosure provision.

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

This is Linda Kloss and I think that in practice some of the process may call for securing an additional authorization under certain circumstances. So, I think that how this might play into our recommendations is to call for greater clarification of that issue, because it...

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

Yeah.

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

It is being done differently.

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 a great idea Linda because I've actually dealt specifically with entities at the state level who have required separate consent and that it was very circumstance. So, I think clarity or at least some discussion around that would be great.

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

I think also some clarity on what OCR considers access when it comes in the context of other laws would be good as well from OCR because for example VA we don't consider the fact that 7332 when it comes to making disclosures to third-parties, whether at the request of the patient or not, we don't consider that access. Given, you know, the best...

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

Hello?

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

It sounds like Stephania got cut off.

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

Yeah it sounds like she got cut off. Okay. So, I think we were following the point there both I think that we can put into kind of our talking points it may help to have clarity around both the other federal laws and the distinction between access under HIPAA and disclosure that may come in there as well as preemption of state laws that maybe believing they're providing greater privacy security whereas the HIPAA preemption would apply to a greater access provision. So, I think that's a...that would be a good clarity as well.

Okay, other comments? What else do we want to include?

We can move to the next slide if you want that talks about the first straw proposal we have, strawman. So, our...and this is dealing with question one that it didn't appear from the conversations that we had and from the submissions that we had the questions that file size should be a proxy for pages. It really should be more precise around the calculation of labor and media and the definition of, you know, search and retrieval if they wanted to provide...as well as some hypothetical scenarios to include the kind of questions two, three and four where they would provide input on the fee structure that may be relevant in each of three circumstances with the general guidance idea I think of if they're offering form and format that are a common electronic media, the providers are, and requests are for something other than that there may be, you know, a greater...it may be, you know, at least fair in those circumstances to charge labor fees whereas again it was difficult to come to good kind of suggestions or discussion points where we didn't have specific hypotheticals because we talked about a bunch of different scenarios.

So, this was kind of straw proposal one, strawman one. Any thought on that? It really does cover kind of the first, you know, four, I guess the first couple of questions. Any discussion on this one?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

...

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

I think this is fine so long as we make that earlier point about defining search and retrieval and the inclusion of the quality checking process.

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

Yes, yes, thank you for bringing that forward, yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is David again, and again this may have been covered in the previous session but I would have thought maybe or suggest maybe that kind of an overarching suggestion is some notion that we want patients to be able to get their data at a reasonable cost and that unfair, unjustified or otherwise inexplicable fees and charges should be avoided. I mean, is there some...I mean, all we're doing is just making, you know...tossing out ideas for discussion shouldn't we start with a discussion that says the goal here is to make it easier to get your record rather than to justify why it's expensive to get your record?

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

Yeah, I mean, I think so, I mean, so we're not really formally making recommendations here we've been asked for some input and positions but I think that's a good input and I think that's generally what we saw from the patient community and what we saw from, you know, PHR providers. And I think that it's also consistent with at least the spirit of what the providers would like to do.

So, you know, others who...other thoughts? I mean, we can certainly have kind of a couple of overarching comments like that...

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

I...

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

Along with kind of the other...yes?

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

I would really support that and I had a couple of other overarching issues and thought I'd bring them up later, but perhaps we even go a little further on that and say, you know, whatever the formula is it would be in everybody's best interest if they be kept fairly simple and I think that our goal is to, you know, lay out an approach that is forward looking to the day when in fact this is pretty easy to share the record through a portal or through some other secure device. And that what we don't want is kind of a repetition of the complex formulas for calculating costs that we've had in the past.

And I think that simplifying this is probably going to help providers perhaps, you know, streamline processes, reduce costs and I think that at this juncture, in that spirit, we should be looking at some administrative simplification solutions.

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.

I don't know if that makes sense, but I completely agree that simplifying the pricing and laying out incentives to really create direct, a more direct route for patients would really be in the spirit of what we're looking for.

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

Okay. Other thoughts? Okay, so I've got...as I've kind of captured this I think we can probably take this strawman suggestion, maybe we want to create a strawman one of, you know, the goal is to provide patients with electronic copies of their medical records and generally fees and costs for providing such records should therefore be minimized. Simplified fee structures should also be encouraged which would help us to meet this goal. I mean, comments along those lines.

And then we could start the, you know, suggestion two of, you know, file size should not be a proxy for pages and then ask for additional guidance on precision around calculation of labor, media and search where HIPAA quality and compliance checks as well as ask for clarity for access in the context of the federal laws versus disclosure and then the preemption of state laws on this concept. So, to pull all those into a straw suggestion.

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

One of the...I did a little focus group to help think through this and for example, you know, rather than taking this as formulas for direct labor would there be some way to categorize, you know, a more set fee for particular tests or procedure results versus an episode versus, you know, a full longitudinal record? Could we create some trunks that were simpler and, you know, would help, you know, provide us really drive down costs and unify this.

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

Yeah.

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

That may go too far but I think that...

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

Yeah, I'm not sure...

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

It gets to the point that...

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

It fits within the scope of what they're looking for but...

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

Right, but I think it makes a point that, you know, we would encourage innovative and forward looking approaches.

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

Any other thoughts on this now that we've made this suggestion one, I think three separate suggestions possibly? Okay. Let's go to the next strawman and see if it can generate some conversation.

Then in future guidance OCR should define search and retrieval and distinguish between search and retrieval costs versus copy and duplication costs. So, you know, better delineation and understanding perhaps clarification between those things perhaps and it may help to look at the FOIA definitions of form and format and search.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So, are we now sort of actually adding to administrative complexity by...

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

By referencing FOIA?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well and defining all these fine grained distinctions.

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

Yeah, I mean, you know, the conversation certainly last week and then...it seemed like a lot was kind of hanging on this, these concepts and if you look back at the...certainly at the legislative record or regulatory record and the comments, you know, HHS, you know, intentionally didn't define things like they did in FOIA because they believed it was a much broader universe of individuals getting access to the data and so they saw that, you know, not having the definition may be...would be more helpful and instead appealed to, you know, reasonableness.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah.

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

So, it's a good question.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And I'm almost...I mean, this is just a sentiment reaction, but, you know, FOIA requests are often adversarial.

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

It's a fight, somebody wants to protect data and somebody wants it unprotected and there is a fight about it. I mean, the whole spirit here is to facilitate consumer engagement in managing their health and the goal is to get out of the way and reduce the costs and the complexity to the point of where at some point it is so negligibly electronic that no one bothers to have these conversations, but bringing FOIA in turns it back into this sort of "it's my data" "no it's not it's my data."

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

Yeah.

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

That's a good point.

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

Yeah, that's a good point.

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

And, you know, I think there are a number of providers who are working under the spirit that, you know, they'd like to provide records to patients at no cost and I think the actions we take need to further that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah and I think the goal might be, you know, arbitrary and "unexplained fees" would be discouraged. I mean, you've all seen the horror stories of \$1500.00 charges for dumping a few pages of your medical record most of which is bundled into something called "fees." You know which is basically, you know, justifying the HIN department or something but it's not related to the cost of producing it.

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

Well, and often it's outsourcing costs...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, exactly.

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

That gets passed onto the patients that's what it is.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Exactly, third-party companies using it to make their money. I mean, again, we're not making recommendations but it seems like the clarity and why it costs what it does is to be encouraged. Hidden fees or unexplained fees not, although I don't know, you know, somebody can just say it's \$2.00 a page to copy, oh, now it's \$5.00 a page to copy.

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

So, maybe...I mean...so maybe, you know, the strawman suggestion one really kind of covers this too and maybe we don't need two and that strawman one is saying, you know, in the context of, you know, hypothetical scenarios that can provide clarity and maybe OCR could delineate what they think in a hypothetical scenario a labor or media, or search and retrieval cost might be in those scenarios but not go to the length of actually defining or having a lengthy definition. Is that what I'm hearing?

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

I think so.

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

Okay. David are you okay with that?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, I think so, you know, I'd probably have to think about it and see it written.

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

Okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And think about it because it's...

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

Okay and we will and that's a great point for next steps we will kind of modify these, come back and send them to you and then hopefully we'll get sign offs so we can submit and we need to get them submitted fairly quickly.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Was there any discussion about the legitimacy of the third-party companies that are essentially trying to make a profit on being the friction between the record and the patient? Did that come up as to whether that itself should be discouraged or is...I mean, you could imagine putting rules in place that would make it not a profitable enterprise to go try to run so they would go away, but did that come up at all or is it just assumed that this cost...that this has to be there?

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

I don't remember that coming up specifically. Others?

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

It's come...well, I think we thought that was beyond scope...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah.

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

Of this inquiry but I think particularly release of information to patients, you know, can be separate from other third-party releases.

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.

And there are organizations that, you know, have chosen to internally hand off releases to patients in the spirit of engagement and only do outsourcing for other third-party requests or, you know, moving these functions back to within the organization. So, I think there is plenty of flux in the industry and it depends on, you know, how easy we can make this electronic transfer and how, you know, how we can create guidance that encourages that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah and that was why I was asking at the beginning whether this was patient-driven or third-party driven.

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Because I can see that being a distinction that does matter. The complexity and risk of a third-party request is much higher if you've got it wrong you're going to get sued, if you understand that this is in fact a patient so there is some overhead in identity proofing that it is the actual patient that the risks go down considerably and the costs ought to as well.

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

Okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

All the way to zero if it's a portal.

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

Right. Other thoughts on...I mean, if you just look real quick, I mean, we only have one other straw recommendation and that one we already talked about if you go down to three. Next slide, please, there.

And we've already talked about this. I think we'll just modify this one to say that OCR should clarify how to handle more restrict or privacy protective state laws if patients want a covered entity to send their record to a third-party. So, it would be both...we could cover both the state and the federal law interaction here and I've got some notes on that and so it's the state laws that may require an authorization for disclosure where HIPAA would preempt it as being less access right protective and then...and so clarity around that and then clarity around the federal law interaction with Part 2 of the federal laws. So, I think that would be our suggestion three.

And then going back up in one would be...would include now this concept of the kind of overarching goal of providing patients with electronic copies, you know, minimizing fees where possible and a simplified fee structure should be encouraged and then go into the file size concept that's here. So, we would cover the overarching goal and the file size not a proxy, we would likely strike the separate strawman for understanding form and format and search definitions and instead rely on the hypothetical scenarios for more clarity potentially.

And then the final one was the state law interaction three. So, other than those and we talked a little bit about, you know, a couple of...have we covered what you want? Do we want to try and write that up and get it back? We're going to have to turn this fairly quickly I think as our only issue so we're time bounded.

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

Stan there...

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

Stan this is Devi from...sorry, can I just chime in?

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

Go ahead.

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

Go ahead Devi.

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

This is Devi from ONC.

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

Yes, please, Devi?

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

So, just to clarify on question number two, so I think the actual question when we drafted it and sent it out was it was talking about whether the producible form and format of the electronic copy that the individual requests essentially affects how individuals charge and I think we gave an example of, you know, an individual who perhaps is using the view, download, transmit capabilities in the EHR and, you know, trying to...

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

Right.

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

Send it somewhere else and so I think just to clarify that was the scope of that question. And I think where that FOIA definition of search and retrieval came in I think that was a separate question and I think that was...

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

Right.

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

I think we decided on the last call just to kind of talk about that because I think Stephania had referenced that that's the way the VA does it and it was...

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

She did.

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

Yeah, so I think that was just kind of...I don't know if we...it was just kind of giving some context to that and so it was just a different way of looking at the information I guess and so I just...

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

Right.

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

Wanted to provide clarification, like we are not, you know, trying to add administrative burden it was just, you know, something that we thought would be helpful to have on hand given that Stephania was talking about it last week.

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

Yeah, so the idea that if OCR wanted to provide comment on how they see this different than FOIA or the...

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

Or just as a way of, you know, like the VA does...uses the FOIA definition in how they charge fees and just...it was just a different lens of looking at it.

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

Right and I think...I mean, I think just hearing our conversation today and last week, and then seeing some of the written comments though I actually think that rather than asking for, you know, specific...

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – 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

Clarity around search and retrieval definitions that they could look at FOIA but then potentially provide hypothetical scenarios...

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – 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

That they would then delineate what they would see in those scenarios as being labor and what would be copy charges, etcetera, or what would be search and retrieval.

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

Yeah, no, absolutely, no, I mean...

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 we will definitely include that when we draft...

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

Great.

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

The final suggestions.

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

Okay, great. So we did...

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

Stan?

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

Yes, go ahead, please.

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

Yes, one other comment that again may be beyond scope but it may be important to clarify in third-party, in relation to third-party, the question what's the position with regard to charging for delivery of information to other providers I think that is still an issue where there is uneven practice and uneven interpretation and, you know, maybe creating some...when we talk about third-parties making it clear that again, you know, we favor policy that requires really providers on behalf of patients to deliver it to other providers without charge or minimal charge, or something.

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

Okay, you know, are there other things that I...and I agree with that Linda, the other thing that I see is that when we answered Q2, and David, thank you for bringing that back up, it does say should the producible form and format of the electronic copy affect how the individual is charged. I mean, I do think that hearing from the VA and hearing from others I think we, you know, we may want to...and this may not answer the, you know, question directly but I do think there is this...there is a concept of where standardized formats are offered in electronic copies and common formats are offered but an individual requests something differently that would be a scenario where we would see a fee being charged to the individuals being more reasonable than a fee being charged where they already have the reproducible...they already have the form and format that is minimal cost or at least there is a cost differentiation in those circumstances.

Yeah, I'm not sure if that responsiveness is what they're looking for but that is kind of built into the idea of asking for, you know, more detailed scenarios where we could provide input, we could create the scenarios and then provide input on them but if they have some that are of...that they wanted input on specifically then we could provide that but in general I think that was the approach that we had discussed. So, I'm not sure if that rises to the level of a talking point or a suggestion.

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

I think that would be a helpful suggestion.

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

Other thoughts or comments from others on the phone?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

This is not about that question but a different one in your suggestion number three, I'm trying to find it here, the distinction of more restrictive or less restrictive could be...I heard confusion, yeah, so you said...

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

OCR should clarify how to handle more restrictive (privacy protective) state laws. There was an opposite interpretation of what more or less restrictive meant...

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

From the perspective of whether it's state or federal and whether it's revealing...

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Or not revealing so I might reword it to not say more or less restrictive but differences, how to establish priority when there are different restrictions between state and federal entities.

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

Yeah, I think that's right and we will rewrite that and try and get your input on it. I think it is something, you know, perhaps it's also language that says, you know, how the HIPAA access request should be considered in light of other federal laws especially those in Part 2, you know, that require...that consider the disclosures and require consent and then at the state level, yeah, it's what is the exact, you know, preemptive, what's the clarification around the preemptive aspect of access requests.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right.

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

So...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

It could go in either direction.

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

Yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

It could be...

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

Yes, agree.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

It's not just...

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

Yes, agreed, yes and clarity on that would be great. You know I'm not sure if anyone from OCR wants to comment about whether we're, you know, we're actually giving, you know, any type of input that's of value or interest here? We've gotten some input from, you know, different stakeholders and had some conversations and were developing some discussion points that I think it's fair to make sure we're touching the topics we needed.

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

Yeah, hi, this is Christina, you know, I do think so, you know, any...if you have any thoughts on the line between search and retrieval and copying that may also be helpful. I know that's probably another...

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

Yeah.

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

Phone call's worth of a discussion but I do think the points that are being made are helpful and certainly the interaction with state law and other federal laws is something we'll be looking at.

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

And we had...I think that's a great question and we had a public comment that I think was kind of on point there too, at least, you know, with the perspective of the commenter was provided and we'll make sure that's available and so, you know, that comment was that, you know, search and retrieval is exactly that it's where you are, you know, looking for and retrieving the document and then once it is retrieved or once you have it then all of the act of shifting and figuring out what should be disclosed in response to the access request and what shouldn't goes to support the part of copy.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I would...this is David, to me it seems and I don't know what the law says exactly so I maybe off base here, but it seems to me that there are two phases one is establishing what fulfills a request and its associated legality and then second there is just the process of copying and distributing the record.

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

So would you say the establishing legality is part of the search and retrieval?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yes, yes, in other words you've got to go find what qualifies, make sure it is covered and that you didn't reveal stuff that wasn't requested...

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

So, others have suggested that the only thing that is part of the search and retrieval is really entering in a search term, getting a result and saying that you now have the record and then taking...once you have the record and start to make the assessments you've made you're actually doing that aspect of copying.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well, I'm...

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

Yeah...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I'm sure...

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

So the distinction being search and retrieval is not...you can't pass fees along or costs along for search and retrieval but you can for copying.

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

It's interesting...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

It doesn't...

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

Historically it would be interesting to know how that distinction got into the law because I think as David said there is a qualitative process in determining what information you need to access to meet that particular request and verifying that, you know, you've identified the right patients and the right data sources, and so on and so forth.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah it seems...I mean, I'm thinking of it in terms of the likelihood of the professionals involved, so some HIM professional is likely to be engaged to figure out what...where is this data and what aspects, what parts of it are available because that's a subtle issue that might require knowledge about 42 CFR 2 and stuff like that and then there is a different individual who actually burns it to a disk or runs it through the fax machine, or, you know, routes it to the printer and staples it up. One of those is a very simple labor cost the other one, the former one, is a more complicated professional fee in a sense.

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

And then the review of the retrieved record to make sure that there isn't any information in there that belongs to another patient and so on and so forth.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, I'm going to...

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

Yeah.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

As the number one.

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

That's that quality check, yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, the expertise to know what should be released and then there is the physical process of actually getting it to cross the threshold somewhere and those are probably done by different people. Although it is a bad idea to write a law about a particular process that happens to be true today, you know, because it...

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

Yeah, exactly.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Won't exist in six months.

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

Yeah, I mean, the public comment that we got, the written submission we got in from HealthPort IOD, which states that they are the country's leading provider of health information management products and services, you know, their distinction was that search and retrieval was fairly straightforward it was determining whether you in fact had the individual's records and then once determined...once you have the records pulled forward either in a hard copy meaning you pull them off the shelf and put them on a desk or electronically, you know, they're pulled into your electronic environment that's the end of search and retrieval and everything that happens thereafter to determine what gets copied, what doesn't, what is sensitive information and what's not would all be part of the copying cost because you determine what exactly can be copied and produced.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well it...I mean, I can understand that but, you know, the decision about what can be copied versus the actual process of burning to a disk or running through a copy machine are not likely to be the same person. I mean, it seems more likely that you'd lump the search and retrieval and, you know, oh, by the way we're going to set a filter to say don't include SAMHSA records and when I do the search and then they hand that off to somebody who produces the actual physical product or the disk, or...I'm guessing, I've never worked in an HIM department, but just...

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

Well, I...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

By skills and judgement those are really two very separate things. A judgement is about what you're allowed to send if there are restrictions.

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

Yeah, well, and this is...these other slides and maybe there's a...I went up...let's go back up to the slide on FOIA and the definition of search on slide 10. You know search there is to review manually or by automated means agency records for the purpose of locating those records, right, which are responsive. So, you know, that seems to be a narrower definition than what you were just describing under FOIA for example.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well, that's a good idea and a good reason not to reference FOIA I guess, huh?

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

But, you know, David is correct in describing how that process is done because you have to verify first of all that you've got the correct patient...

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

Right, patient...

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

So there's a...

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

Yes.

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

Master patient index step. And then the range of records that fulfills the intent of the request and, you know, whether they're all included in the electronic health record or whether it requires accessing other imaged records or paper records or some combination.

And then once you've grabbed them then the review to make sure that everything in there is applying to that particular patient and that there aren't any exclusions that need to be dealt with separately and that is the process.

And then when there is, you know, a release of information service there is some point of demarcation between what might be done by the provider and what might be done by the third-party service, you know, some may just do the copying and grouping, and mailing and some maybe doing that front end quality check also.

So, it just isn't one process and we've got a law that kind of cuts and sets an artificial differentiation between search and retrieval and the rest of the process, and, you know, that's just kind of why this is a complex...why this is a tricky issue.

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

Anybody else have a position on this as we're trying to help out and just get some perspective on search and retrieval at this point and the copy.

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

It is just kind of an artificial distinction.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well, I'm...this is David again, I'm sort of struck now that you have this FOIA statute up there, it really maybe not intentionally, but it distinguishes three steps search, duplication and review. And it calls out what review is, direct costs incurred during the examination of a document and determining whether the document must be disclosed or in determining whether any part of the document is exempt from disclosure. So, I'm guessing that's the black marker through restricted parts of information that could be different from search.

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

Right, so is that part copy costs or is that search and retrieval?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

No I think duplication is the actual, you know, I'll call it mindless copying meaning no experts need be involved with duplication but the search is an expert and the review is an expert perhaps not...

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

Agree.

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

And you receive some commentary that we had as kind of the supporting document from...on this topic as well and they kind of went back and forth on the same topic. And the comment from HHS at the time is that, you know, we conclude that FOIA was developed to reflect the relatively uniform government cost and that this proposal will apply to a broader range of entities therefore we propose the entities simply charge a reasonable cost-based fee. Yeah, so, it doesn't...yeah, well any other thoughts? Any other positions on what you think should be in or out of search and retrieval?

Okay, at least we had some good conversation around it. I'm not sure we have a definitive we can certainly include kind of a key discussion point.

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

Well, the reality is even if there isn't an allowable charge for the search and retrieval that still is a process that needs to be done by a knowledge worker as David said.

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

So, would that...I mean, so finish that...so does that cut for it not being included or included?

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

Well, I guess I was just assuming that search and retrieval is excluded..

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.

And just making the point that there is cost associated with it...

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.

Even if it is excluded.

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

Yeah, no question, yeah. Okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, some of this is just the cost of running a hospital you can't charge a line item for every single thing that happens, less and less so.

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.

And that's why going forward I think that it would be so advisable to, you know, try to find a way to simplify this because that...

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

This is...

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

Isn't very helpful.

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

This is Gayle Harrell, I'm very late getting into this conversation because I had another meeting I had to be on and in reading the slides and going through things I had some major concerns when you start bringing up FOIA and what that all means.

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

Yeah.

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

And I don't know whether that conversation has taken place or not but...

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

Yeah.

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

Once you get into the FOIA milieu you are in a different ballgame, I don't know that we want to make this...we want to pattern ourselves after that in any way that's a very adversarial process normally.

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

And Gayle that's exactly what the conversation was, you're very consistent with what I think David was talking about at the very beginning on that being adversarial. So, I think that's consistent.

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

I think...

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

We...please continue.

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

It makes me nervous when I started reading all the slides and looking at them and saying “oh, my God, I hope we’re not going down this whole FOIA route.”

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

Yeah.

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

Second question, second thing I want to say is that I think this pretty much is standard across the medical arena on how you handle records requests and we want this to be as easy and simple, and uncomplicated as possible with some reasonable charges and when you get down to start defining what they are it becomes very complicated and then you wind up in all kinds of issues, you know, if there is a way to set a reasonable standard without getting into the minutia we want to make sure the records are available, reasonably accessible, you know, accessible to patients, accessible to other providers, but I just get real nervous about setting specific charges or limits on charges, or whatever, or even going down that road.

This gets me into a real arena where you’ve got to market in place out there that we want...we don’t want people charging exorbitant amounts and one provider charging another provider exorbitant amounts, because you want a free flow of information, you want reasonable access and free flow of information without excessive charges without getting down into heavy duty regulation that can...

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

Yes, you are consistent with...yes, you are consistent with what we’ve...how we’ve been discussing this and David in one of his earlier comments said the goal was to provide patients with electronic copies of their medical records and generally fees and costs for providing such records should therefore be minimized, simplified and fee structures should be encouraged as kind of the suggestion of the talking points that we have on that.

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

Yes.

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

So, I think that’s consistent with what you just said and then we’ve kind of removed the straw proposal two and kind of put it in other places so it is not...it’s clear we’re not suggesting they follow FOIA, we were really...

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

Oh, thank you.

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

Yeah, we really were meaning it to simply invoke a conversation around search and retrieval and copy costs and then we had a similar request from the Office for Civil Rights to have just a brief conversation to give some input on where we thought a delineation may be so that's kind of where we were. But I think where we are landing is very, very consistent with what the...the comments you just made so that was spot on.

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

Terrific, thank you.

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

Absolutely. Any other thoughts? And Michelle maybe we should open, let the public know we're going to open the lines because I think we're winding down and if we get some in the queue we can go to it and come back.

Public Comment

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

Okay, Lonnie, can you please open the lines?

Lonnie Moore – Meetings Coordinator – Altarum Institute

Yes, 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. Thank you.

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

Okay and so, you know, where we need to try and get to by the...in the next 20 minutes or so is get comfortable with where are on our suggestion and could you remind me again either Michelle or Devi on where...what our turnaround time is and when we kind of finalize and submit?

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

Hi, this is Devi, so I think we are looking to finalize it within the next week I would say, I mean, Michelle I'm not sure if you have any further...

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

So, we can...so we'll come out of this, we'll...I've made some notes, we'll make some modifications...

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – 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

To the suggestions specifically...

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

Absolutely.

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

And kind of limit this down to the suggestions.

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – 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

And then get that back to the workgroup, you'll have one more pass to take a look and provide certain edits and then we'll be ready to submit.

Devi Mehta, JD, MPH – Senior Health Privacy Analyst – 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

So, you know, the suggestions where we're kind of landing is, you know, the general goal as stated by David and Gayle very well on the goal is to provide patients electronic copies of their medical records, then the comment that file size should not be a proxy for pages.

We asked for potential hypothetical scenarios when they provide guidance so that they can kind of help work through where, you know, labor search and retrieval costs might be in a hypothetical scenario rather than coming out with stringent definitions.

And then the general comment where the provider has a standardized form or formats that it offers for free or at low cost to patients and if the patient request a different format the provider would likely be more justified in charging labor costs associated with producing that format, that's kind of a general comment. But then the opposite, if they don't then it's hard to justify a high labor fee because of a suggestion for a certain format if it's a standard format from the patient.

And then finally, the clarification around the preemption of state laws and the interaction with other federal laws and we'll have language around that. So, that's kind of where we've landed as far as being able to put it together.

Other thoughts from the workgroup? Does that seem like we're...that's kind of where we are?

Kathryn Marchesini, JD – Deputy Director for Privacy Policy – Office of the National Coordinator for Health Information Technology

I was going to say, Stan, this is Kathryn Marchesini, from ONC, I just had a question. I was looking over the questions again from last week there was a specific one that talked about business associate and the cost that maybe in addition to...

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

Oh, right.

Kathryn Marchesini, JD – Deputy Director for Privacy Policy – Office of the National Coordinator for Health Information Technology

Let's say it's a covered entity that was just providing access, so I would just, you know, maybe ask the group, I know that there's conversation around a reasonable cost and that labor cost, you know, should be, you know, included, but I know early in the call there was a comment about, you know, the cost being completely passed onto the patient, the group didn't think that this was probably the best approach.

So, I was curious if the group had any other thinking about if the business associate in some way had to upload or reload, or in some other way get the information to the patient even though there will be additional labor involved what kind of...how should that cost be calculated?

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

And so part of this issue that...at least the way that we were talking about it before is that...it's due to some interoperability issue, right, between the EHR and the application that is used to produce an electric copy for an individual and so the first question was, you know, is that a reasonable fee that should be passed on or a reasonable cost that we should pass onto an individual when it's the interoperability within the institution that causes the issue. Certainly the patient said "no." But the providers, you know, looking realistically at their circumstance said, you know, we should be able to pass some type of fees along. So, that was kind of the input so I guess the question for the group is along Kathryn's question, is, you know, which way do you fall on that and if it is that you charge fees, what is reasonable?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

But it's a little different, this is David, to outsource this work to a third-party isn't an interoperability issue.

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

I mean, the hospital is basically saying, we don't want to mess with it we're going to hire somebody to do it and we're going to let them make money by charging whatever fees they want.

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And we may...

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

Well, the question...okay, so are you saying that the question isn't a legitimate question or I mean...because the question was pose it as an interoperability issue.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, I think that's a wrong question. In other words, those are two separate things. If the hospital is producing the report themselves and some parts of their report are more expensive to produce than others due to their internal architecture that could be an interoperability issue and I think, you know, we could debate that, but if they choose to hire a third-party company to produce the reports and charge service fees for doing so that's a business decision that doesn't have anything to do with interoperability.

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

I think...

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

I would agree with that distinction and I would add that, you know, the internal interoperability issue, you know, would be covered by whatever guidance is issued on reasonable labor costs, because having an internal interoperability issue does increase labor products.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

And then...but I think, I mean, this raises an interesting, you know, new question in a sense, let's say a hospital just doesn't really want to share this data at all for whatever reason, they're primordial data blockers, so they just hire a third-party company that charges \$5,000.00 fees for producing a copy of the record is that legit? I mean, clearly, no morally, but is it...would it be allowed under the suggestions that we're making?

You can't just absolve yourself of the total cost of access to the record by letting the third-party charge an arbitrary amount because it's a different entity I would propose. I don't think that...

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

This is Gayle, I...

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

I'm not sure...

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

I'd like to jump into this too and I really think that there are costs of doing business providing records is a cost of doing business and if you define it as such you can have a reasonable fee to how you...and we should not be in the internal business decisions of an entity, but you can simply say there must be a reasonable fee for access. If they, you know, decide to outsource it they still can only charge a reasonable fee. I don't think outsourcing absolves them of that responsibility.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah.

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

So, you would set a reasonable fee...

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

Agree.

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

Based on if you're doing it all internally, but I think the issue here is, at least as I read this question and maybe we can ask for clarification on how they wanted us to answer this question, but I read this as if there is interoperability issues between the EHR and the software used to create the copy for the individual could they charge labor costs for reconciling that interoperability.

They also have the subtext here that says, and the business associates have to do this. So, maybe it's two separate questions, but either way it seems to be an issue related, at least in part, to interoperability.

Because I don't know if anyone from the Office for Civil Rights wants to clarify, you know, the question if we're considering it correctly.

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

Hi, this is Christina, I do think there are two separate questions here one is the interoperability question and the other is the outsourcing question.

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

Okay.

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

So, it might...

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

So, increased fees for outsourcing or increased labor for interoperability, okay.

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

Yeah, I do see them as distinct and, you know, it might be that we need to address both issues.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

So, this is David, I'll go out on a limb and say that, you know, with the changes from the Omnibus Bill in terms of how HIPAA is interpreted with respect to the business associates those are now essentially lumped in with the covered entity. Maybe a similar logic applies here.

If you choose to outsource your release of records work you're still liable as an entity for the total fees and they must be reasonable. So, the outsourcing company has to make business sense to you because you're accountable for the reasonable fees the same way that if you outsource, you know, your database services they're still accountable, you're still accountable for the HIPAA privacy violation should there be a breach. You don't get out of it simply because you outsourced it. So, you shouldn't get out of the requirement for reasonable copying fees simply because you chose to outsource.

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

So, the way that I interpret that David and that actually...I think that's probably true, so the way I interpret that is that with respect to the outsourcing, outsourcing should not...it would not be legitimate to pass on increased labor fees associated with outsourcing...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right.

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

Is I think a...is a broad summary of what you just said.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah, yeah.

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

Okay and then for interoperability issues where the institution has their own interoperability issues and that results in increased labor costs is that a reality that has to be addressed in fees passed through or is that also something that isn't the patient's issue?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Well, I think that's going to come down to what we define as reasonable fees.

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

Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Are we going to define that as, you know, just output, you know, it should never cost more than "x cents per page total" and you can divide that up internally however you see fit or are we going to allow itemized bills that still have to be "reasonable" and if you're going to allow itemized things like the difference between search and retrieval, and copying, which I would like to think we didn't do, but, then, you know, I mean, you could charge for floor space and air conditioning, I mean, where do you draw the line.

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

Well, that's why I think we were recommending in favor of simplifying from...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Right.

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

The previous or from the current state and being future focused assuming that with increased interoperability the costs should come down and those savings, you know, we need to get...we need to get to zero, we need to be able to get to a point where we can fulfill a request for a patient through existing portals or other mechanisms and that that's the more standard way of doing business.

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.

I just think we have to...we just have to drive the current state which is highly variable and costly.

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

Okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

Yeah.

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

Well, we're...do we have any public comments?

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

We do.

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

Okay.

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

We have Adam Greene. Adam as a reminder public comment is limited to three minutes. Do we still have Adam?

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

Thank you, hopefully you can hear me. This is Adam Greene from Davis Write Tremaine, I'm also at the AHIMA convention where there are thousands of health information management professionals who would be very interested in this discussion.

I just wanted to raise three points, one is that this has become a very significant area of litigation, this area of patient costs or charges for requests from patients because a lot of these requests are actually, while they're signed by the patient, they're coming from plaintiff's attorneys and when they feel like the costs are inflated they then either file litigation or file complaints with Office for Civil Rights.

And there is a theme, you can see it when you search amongst plaintiff's attorney forums, that the whole health information management process is essentially some sort of profit generating scam. I just wanted to clarify that can't be further from the truth.

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

Yes.

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

I mean, it is not a matter of simply, you know, in the paper world taking a folder and throwing it into a copy machine and in the electronic world it's not a matter of just pressing print on an EMR, you know, there is a significant time and it can take hours for someone to go through and extract the information, once they've identified the correct patient extract the information and make sure that within the EMR it's not some other patient's information, that it is responsive to the request, it's a very significant process that still exists today and I would caution to...we want to be sensitive because whatever suggestions are made here if they are made on the misguided belief that there is no cost here that's something that's going to be used by litigators to challenge what in fact is actually a very significant process.

I can also tell you that where it's a third-party release of information company, as my second point, it's not a profit center, you know, they do not, at least the ones that I'm aware of, are not seeking to charge a profit for a patient request. They are also looking to just recoup their costs. They bring an expertise and a technology based on economies of scale that are very valuable and would be lost potentially if they are not able to receive reimbursement for their costs in this area.

And the third thing would be that historically there's been an exclusion for search and retrieval costs but inclusion of essentially the rest in the copying process including there is guidance specifically talking about extracting and compiling.

On the electronic side there still is search and retrieval it could be the rarer circumstances of having to go into electronic archives to pull out something, more frequently it may be just going through the...there are many patients with the same name and making sure you've got the right patient, you know, that certainly should be excluded as search and retrieval but once you've identified the patient the process of extracting and compiling that information, because it's not just pressing print it is going through episode by episode pulling that information out and putting it into a system where you're going to be able to copy it and have a record of that copy, that is something that is a significant process that, you know, historically on the paper side was always covered under HIPAA and, you know, I would recommend that it continue to be included as reasonable and appropriate costs of that copying process. Thank you.

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

Great, thank you very much.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation

You still...

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

We don't have any other public comment.

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, I think we have some...we can pull together some thoughts and get this back out to you. I think we've got a pretty clear position on many of these things and just probably discussion points on some of the others. Last thoughts as we wrap this up? Okay, well, I really appreciate the robust conversation and I was wrong I didn't think this would take the full 90 minutes.

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

You jinxed us Stan.

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

And fortunately it did because this was a very good conversation and I think we've captured much of the comments of individuals. So, we will endeavor to turn this around fairly quickly and get this back out to the working group for finalization and then get this over to the Office for Civil Rights for their consideration. Michelle, anything further?

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

No, I think that's it.

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

All right, thanks so much everyone for calling we appreciate it and we'll talk to you again soon.

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

Thank you.

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

Thank you, Stan. Have a great day everyone.

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

Okay, thank you.

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

Bye-bye.

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Thanks.

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Thank you.