

**CENTER FOR DEMOCRACY AND TECHNOLOGY**

Fireside Chat and Panel Discussion  
HHS Rule Limiting Law Enforcement Access to Reproductive Health  
Records

April 29, 2024

*REMOTE CART CAPTIONING PROVIDED BY:*

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>> ALEXANDRA REEVE GIVENS: The focus is on protecting human rights and democratic values in the Digital Age one big work of ours is on privacy which is why we're here today to talk about the latest rulemaking from HHS' Office of Civil Rights on protecting reproductive privacy and HIPAA. We're here with Melanie Fontes Rainer who leads that office and after our Fireside Chat which will last for about 20 minutes we'll transition over to a panel of experts who will talk about the rule and its impact for patients and for providers it's a wonderful group it will be moderated by Andy Crawford on our senior privacy and data team we have Erin Mackay who is at the National Partnership for Women & Families Alice Leiter, who is counsel at Manatt Health and Lisa Myers a senior Washington counsel at the American Medical Association but first of all Director Fontes Rainer we're so happy to have you here and would love to kick off a conversation about the rule but before we even go into that not everybody is familiar with your office so I would love for you to talk a little bit about that and the work you do.

>> Thanks for the opportunity and question the Office of Civil Rights is a national facing organization at the U.S. Department of Health and Human Services what folks don't totally understand is most Federal agencies have a Civil Rights Office so ours is

for things that are funded and out of the U.S. Department of Health and Human Services we're the only Civil Rights Office that not only does civil rights which is a big mandate civil rights of age, race, disability, sex-based discrimination, among other things, we also are in charge of HIPAA farther department so a lot of organizations have two separate offices. We at the Office of Civil Rights have one organization that does that we have offices in 11 cities across the country so there might be a financial location no matter where you are in the country but we have an office in Washington D.C. and staff all around the country our mission is to make sure you can access healthcare free from discrimination and we want to ensure your protected health information your data your security your health records are secure and kept private and those are our mandates under HIPAA which we take that charge very seriously and it's quite if you think about all of our work a large bucket of our work is HIPAA related so whether it's cybersecurity or the privacy rule so it's really important work and we appreciate the opportunity to be here with you today.

>> ALEXANDRA REEVE GIVENS: As I mentioned privacy is core to CDT's mission we file comments for the rule and generally thinking about what reproductive privacy looks right now in the 21st Century and after the Dobbs decision. Would love to hear kind of your perspective on the rule that you've just issued. And in particular the value that it has for the patient-doctor relationship and how we keep trust in the ability for people to have those conversations and know that information will be kept private.

>> MELANIE FONTES RAINER: Yeah, so I think we all think of -- I think first off there's a lot of misinformation about what HIPAA does and does not cover just fundamentally when you talk to people they say oh it's my medical record you and I are both lawyers that work in the medical case we know that's not always the case but I think what this rule does is really tries to protect even that notion of what privacy is with respect to our providers. So we know that if you don't trust your doctor, if you don't trust your provider your Nurse Practitioner whoever you're seeking care from that can impact the kinds of things you're telling your provider that can impact your visits and the relationship you have with your provider and ultimately that can have an impact on your health outcomes we know with Dobbs that we know protected health information peoples' medical records is more likely to be used for investigatory purposes.

To understand what kind of healthcare people are receiving in the first instance in a way that I don't know that many people would think, I'm going to my doctor. Somebody

might be looking at my records to determine if I had a particular type of exam.

If I had a particular pregnancy test, if I had a particular reproductive healthcare service.

So we're trying to foster that protection. That protection is certainly a major tenet of HIPAA itself when they created HIPAA in fact Congress literally said to HHS go create this privacy standard it's important we know it's important for care coordination and for health outcomes but also making sure that Department had that ability to do so.

So post Dobbs we know that there's a lot of distrust in the space and frankly with doctors, too I've had doctors literally tell me I'm worried about my patients' records. We're considering doing X or not even -- keeping things in the record because they are worried about how these records might be used in their state, outside of their state and overall. And I just think these are things that, look, your healthcare is important.

Your healthcare matters. You shouldn't also have to go to your doctor's office worrying what is the paper trail of my records. And how is that going to be used against me or my provider in the first instance so this is really meant to reestablish that medical trust. And to make sure people don't feel so scared that they can't go seek that healthcare they might need in the first instance.

>> ALEXANDRA REEVE GIVENS: Digging more into the weeds can you walk through what the rule does and what protections you're offering for people.

>> MELANIE FONTES RAINER: The new rule updates the HIPAA privacy rule currently as most folks know but quick snippet currently under HIPAA there's permissions to use with respect to use and disclosure of health information we put out information after Dobbs to clarify folks understand HIPAA doesn't require use and disclosure of data only in two instances for the HIPAA right of access and when there's a breach so we put that out what we got back from a lot of individuals, patients, providers, organizations, was this isn't enough.

And we know that there are many instances even under the current state of the HIPAA privacy where people are just handing over data and it might be affecting health outcomes, patient-provider things et cetera we went a step further to say this will actually prohibit use and disclosure of protected health information when it's by law enforcement for the purposes of administrative, civil, or criminal investigation or to impose liability on that individual or that provider. For the mere act of seeking lawful reproductive healthcare which can be abortion. So we went a step further to say these

aren't just permissions we're actually prohibiting it for one of these prohibited purposes to really tighten that up and empower providers because again, there are providers out there who are very sophisticated in the space. They've been in this the long game. A lot of abortion fighters, they know that they don't have to hand over certain things or that they have some discretion in when they do but I think what Dobbs did was ripped that open to not just abortion providers and it said to every single provider that's in your chain of healthcare whether it's your dentist or you know you go to an emergency room and have a pregnancy test because you're having some sort of surgery you now have a medical record that might confirm whether or not you're pregnant and that is valuable information to folks who want to identify people who are getting healthcare.

And so I think this empowers providers in that respect. It gives patients that peace of mind and clarity so that they know that their providers are empowered they know that that information will be private and it also allows for continued actual law enforcement functions. A lot of people have said to me, doesn't this mean that this is infringing on law enforcement? I mean I run a law enforcement -- like OCR is a law enforcement agency. As long as I'm not using this information for prohibited purpose I'm still able to get this information if I go through the process the rule lays out and I think it's an important step to flag.

>> ALEXANDRA REEVE GIVENS: You talked about a couple of important examples so people understand how this rule will act in practice another one that's top of mind for a lot of people is information that pharmacies hold. So in December of last year we saw a letter from Congress that came to HHS followed by a whole bunch of newspaper reporting about how pharmacy chains were actually handing over peoples' medical records or patient information without getting a warrant first.

Would love to hear your take on how this rule applies to that pattern.

>> MELANIE FONTES RAINER: Yeah I'm sure you and your team have read as have others this rule. Hopefully everyone has read it by now.

But.

>> ALEXANDRA REEVE GIVENS: Page for page, every 200 pages, people.

>> MELANIE FONTES RAINER: But seriously you should read it.

(CHUCKLES).

>> MELANIE FONTES RAINER: I will say our actual preamble talks about this letter that was sent to HHS. We've had conversations with Senator Wyden and his

team as well as other senators on this letter. Yes, it's important to show people. Because again, people think, my information is protected by HIPAA, I'm safe. What they don't understand is that under the current state of the rule, before this rule goes into effect, that's not always the case. And even in instances where folks can push back, you know, look, you're on unequal footing when you are at the front desk or you are at a pharmacy counter and you are on the other side of someone in uniform or someone holding a form that's just a fact that's not something I made up that's just like life, right?

And what we also don't think about like the investigation itself was on large pharmacies. Very large pharmacies across the country.

So not a small provider. Not a small dental office somewhere where it's just the front desk person running these things these organizations really need to be thinking about what HIPAA does and doesn't require also with respect to the new rule how they will be compliant with respect to the warrant requirement we talked to Senator Wyden, I know he likes parts of this rule so we're excited to work with him and opportunities he thinks more about HIPAA overall and how to make this stronger overall for patients but it is something we're aware of and I think it is just one of the ways in which people show this rule might be helpful.

Because again these pharmacies were just handing over information they were not required to. Now, I know like it's not my investigation so I really can't comment on what they did or did not receive in this investigation.

We also know how HIPAA works so I think this is a really important step because they will be empowered now to say no I can't give you this information unless they know it's not for one of these prohibited purposes and there's an alternative piece of the HIPAA privacy rule that they are able to get the information from which is important.

>> ALEXANDRA REEVE GIVENS: Part of the benefit is clarity it's not to just their discretion do they or do not comply there's a rule that guides them.

>> MELANIE FONTES RAINER: Absolutely and the preamble we are as clear as possible so providers feel empowered to do this these are giant pharmacies but HIPAA applies to everybody, small, large, extra large, so on and so forth we know at one end of the spectrum sorry I'm not using my microphone at one end of the spectrum you might have a General Counsel or a privacy officer or a firm you use for this stuff at the other end it might be the same person answering the phones who is also required to say

whether or not someone's records are going to go out. And I just think we're trying to do a lot of information sharing but also making sure organizations, large partners, they feel empowered to help share this information because we're trying to be as clear as possible to help protect peoples' privacies.

>> ALEXANDRA REEVE GIVENS: Now let's talk a little bit about the rulemaking process. So full disclosure CDT filed comments a number of the groups in privacy advocates that we work with also filed comments we were joined by many others you got over 30,000 submissions. Can you talk a little bit about some of the trends you saw in the comments? How the agency responded to them and in particular if there were changes from the Proposed Rule to the Final Rule as a result of the comment process.

>> MELANIE FONTES RAINER: Yeah, of course we received 30,000 comments which is actually quite a lot for a HIPAA rule because HIPAA comments aren't typically short or simple. So we did receive a lot of comments and went through all of those comments. I think both on the frontend and the backend of this rule we did a lot of Listening Sessions I personally have been to almost all 20 states that have banned or restricted abortion care.

And those conversations were largely directed by President Biden's Executive Order and those conversations are about compliance.

How do we follow the law? What does this mean for us in a lot of those conversations we heard things like I've had doctors in certain states tell me, you know, my patients if they get pregnant and want to stay pregnant and they are high risk and if I tell them if I were their loved one I would tell them to leave the state. And you know that should be shocking to many people.

Right? At a doctor telling their patient that they don't think they are safe in a particular state now look this rule doesn't change that unfortunately. That means we don't actually touch access in general. But this rule would allow that doctor to help that patient navigate the healthcare system and to protect their privacy.

And we got a lot of comments from organizations, providers, patients, a lot of lawyer organizations in states. So I think we were pretty responsive to the comments overall. I think we'll look forward to working on the next step of this which is education trying to do outreach with respect to organizations. The rule largely tracks the proposed so not a ton of changes the biggest change folks are aware of is presumption happy to talk about now or later in the conversation but it was one of the changes.

>> ALEXANDRA REEVE GIVENS: I would love for you to talk about it.

>> MELANIE FONTES RAINER: We got a lot of comments from largely provider organizations and providers so under the rule construct if it's lawful care, it is allowed to be protected under this rule. What we got a lot of comments, well if the patient is like -- if I'm in a banned abortion state and my patient leaves my state to go get healthcare somewhere else how am I going to know for certain that the care was lawful I don't I didn't provide the care my patient traveled I can assume my patient went to a provider and got lawful care but I didn't provide that care so the presumption itself would allow that individual -- that individual provider to presume the care was lawful unless they had actual knowledge or some other reason to think that it wasn't lawful in the first instance. The presumption itself can be overcome in those instances where it doesn't do those things but that was a pretty strong comment we got from a lot of providers. Was to say I'm not a lawyer and we're asking doctors to do so much these days doctors are not lawyers, lawyers are. So could you please make this clearer and we did that through the Final Rule.

>> ALEXANDRA REEVE GIVENS: One of the big questions I think is going to be implementation.

So having patients and patient advocates know about this rule and kind of know what it means for their own privacy, and then of course the provider compliance piece of this, too. Can you talk a little bit about No. 1 how you're raising awareness of it and No. 2 what you think compliance looks like? Like what steps will providers have to take now as they get ready for the rule to go into effect.

>> MELANIE FONTES RAINER: The rule itself takes effect in June of 2024 however we won't start enforcing it until December of 2024 which means folks have time to get ready. It is an update to the existing HIPAA privacy rules so much of that is staying in place so there isn't that much more to do and I would argue given that it was a discretion with respect to permission in the first instance it's just solidifying that in a way but things like the notice of patient privacy those will have to be updated and we have a timeline for that in the rule making sure that it happens so folks understand what is and what isn't required under the rule. Our office is a small organization.

However, again, we try to work with organizations like yours or some of the major medical associations or insurance associations and others to try to educate as much as possible because frankly that's the best we can do. I don't have a budget to do

commercial -- I'm not CMS I don't control a sixth of the GDP.  
(CHUCKLES).

>> MELANIE FONTES RAINER: I think that's what I think it is. But you know so we try to do as much outreach and education as possible we have two videos up on our website right now one in English one in Spanish they will be dubbed in different languages coming soon as soon as that's done a Fact Sheet a press release we'll think about more webinars so we're actually planning regional webinars in each of our regions both for this and some of the other rules we have coming out in the last two weeks I think we're trying to do as much as possible but also if you're watching this and you think oh it would be really helpful to have OCR come to my regional event or it might be helpful for OCR to do a specific Fact Sheet or something let us know. We're open and willing if we can.

>> ALEXANDRA REEVE GIVENS: Watching the press conference last week where the Secretary talked about this rule and you were up on stage shortly after him, one of the things he really seemed to be focused on is patients knowing their own rights and saying, you know if people are violating this we want to know about it. So can you talk a little bit about what this looks like from the patient perspective? No. 1, raising awareness. But No. 2 if somebody thinks their information is being shared inappropriately, what do they do?

>> MELANIE FONTES RAINER: Yeah so that's a good -- it's a good flag and of course the Secretary is so wonderful for giving privacy this platform, which truly we applaud.

Yeah, you know, I think a couple of things. So OCR on a regular basis does videos. Newsletters.

Technical assistance guidance. Has enforcement actions I think if you want to sign up for our website that's one way to track those things.

So you can go to [HHS.gov/OCR](https://www.hhs.gov/OCR) that's our main page it has information on HIPAA it has places you can sign up for listservs I think that's a good information channel.

Now, do I think like my mom from Phoenix is going to sign up for OCR HIPAA loop maybe because I'm her daughter but probably not.

And so if you think that your privacy rights, your HIPAA rights, have been violated you can file a complaint with OCR again [HHS.gov/OCR](https://www.hhs.gov/OCR) it tells you how to file a complaint you can go through that process if you're not sure if you should file a

complaint or if you're from an organization reaching out to us or one of our regional offices is always a possibility but generally speaking, you can file a complaint with OCR and there are a lot of actual consumer-facing resources on our website and we're trying to do a lot more of those we just put up two YouTube videos for example we tried to distill this rule as simple as possible to try to help drive information and empower consumers in the first instance.

>> ALEXANDRA REEVE GIVENS: The final question to end is situating us in the broader conversation around privacy and in reproductive privacy and in light of where our nation is right now we've talked a little bit about the limits of HIPAA there are the powers of HIPAA and then there are the limits of HIPAA as CDT is a privacy organization is very focused on some of those limitations and what we do for nonHIPAA covered entities, nonHIPAA covered data how we strengthen those protections for example through privacy legislation. Through strong enforcement by the FTC to make sure that people are living up to their privacy obligations.

You're the cop on the beat for the HIPAA covered conversation and some of the other work that you've done is for example reminding medical providers that if their website is tracking information about their -- the visitors to their site that may well be protected health information so would love to hear just a little bit about your broader efforts beyond this rule and anything else you would like to share.

>> MELANIE FONTES RAINER: Yeah you gave some good flags there and I can extrapolate on those a bit more so we cover some of the things on your phone but most of the things on your phone are not covered by us which again that's I think a myth of many people with HIPAA. So we actually put out guidance it's been two years now. We put out guidance FTC put out guidance to say, hey, you are going to be your best privacy advocate in this space.

Frankly like I care a lot about your privacy but your privacy really is in your own hands. So being very diligent about what are you downloading to your phone? What are you storing on your phone? Don't store protected health information on your phone. Think twice about free applications you might use. They might be selling or using your data in a way that might not be up to your choosing or really protect your privacy in the first instance. Things like that we think are super important we put out telehealth guidance with respect to phones, phones can be a really helpful option both to meet civil rights obligations for persons who say can't use utilize certain technologies or may live

in communities where they don't have access to broadband internet things like that those are ways in which you can receive healthcare and they might be helpful in protecting your privacy.

And then I think you talked a little bit about web tracking. We know we put out guidance now over two years ago we just updated it in September of this past -- September of the past year. No, is that right. No, March. Excuse me. March of this past year we just updated our own guidance but this guidance is respect to like Meta or Google Pixel because we know hospital systems are using these they are not bad to use but you need to make sure if there's a disclosure breach we have seen cases like that pop up as of last week so it's really important to remind folks that that guidance is an extension of our HIPAA rule we're trying to be responsive to the types of questions. Obviously we're getting sued on that I can't say that much but I think it's a good flag so folks have visibility these are ways in which even your own providers might be trying to improve your health experience but may be using platforms that otherwise may expose your data then I think overall we work really closely with the FTC. We have regular meetings with them. We work really closely with our partners across the department, FDA, ONC and others and may go sure as Congress thinks about this issue and I know there's some bipartisan support in this space we're supportive and want to be at the table and make sure we're helping as much as we can.

>> ALEXANDRA REEVE GIVENS: That's great even though this rule is focused on reproductive information the broader issues you're talking about provide -- look at medical issues across the board and make sure there are strong protections in place for that type of sensitive information.

>> MELANIE FONTES RAINER: Yes, absolutely.

>> ALEXANDRA REEVE GIVENS: Again thank you, Director Fontes Rainer thank you for joining us today and we'll transition to our panel. That involves us pulling up some more chairs so bear with us for a moment as we do that. Thank you.

(Live captioner standing by).

>> Well hi everybody we're transitioning to the panel portion for folks who don't know me I'm Andrew Crawford a senior policy counsel at CDT I help lead our health privacy work. We just had a fantastic Fireside conversation but now we have more experts to take a slightly deeper dive into the rule we have folks from many different constituencies represented so we're going to ask this panel of experts some really fun

questions. But I should introduce them first off we have Lisa Myers who is a senior Washington counsel at the American Medical Association's Division of Legislative Counsel. She handles health data privacy and security matters including HIPAA. Prior to joining AMA Lisa worked at HHS' Office of Civil Rights.

Contributing to several recently published rules on privacy and health information. Lisa also served in the Office of General Counsel for major health plan for 10 years overseeing implementation of the first iteration of HIPAA. Next we've got Erin Mackay. Erin is the Managing Director of health justice at the National Partnership for Women & Families she supports a portfolio of health justice projects focused on system transformation, health equity and maternal health. Erin is a respected patient and consumer advocate with expertise in health system transformation, patient engagement and digital health. And last but not least we have Alice counsel at Manatt Health who focuses on health information privacy new data use cases and data policy and health regulatory issues. Before joining there she served as Vice President and Senior Counsel at the health initiative where she helped develop privacy framework to govern health data not covered by HIPAA.

>> With CDT.

>> ANDY CRAWFORD: With CDT.

(CHUCKLES).

>> ANDY CRAWFORD: So before we get into questions with the panel I want to remind folks you can also ask questions we'll try to save some time at the end for questions for folks in the room you conveniently have a pen and note card under your seat if you feel inspired to ask a question please jot it down on the note card my colleague Eric on the side here will help collect questions and we'll at some point pass them up to me so we can ask the panel.

For folks online, you're not left out. There's fun for you, too. You can submit questions via an email. The email address is [questions@CDT.org](mailto:questions@CDT.org). Or if you're on Twitter, you can use #CDTquestions. At our Twitter account which is @sendemtech. Housekeeping aside let's jump into some questions like so many panels up here CDT filed comments the Proposed Rule last year. And among the things that we called for were ensuring that reproductive health data was captured definitionally by the rule there were real meaningful limits on the sharing of health data. There was strengthening the rules -- the proposed rules attestation requirements and an indication component that

we actually talked to Alex and Director Fontes Rainer talked about earlier so we're happy to see the Final Rule address some of these changes and we know there's still more work to be done okay to the panel and we can just go down the row to start I would love to hear folks' initial first reactions to the rule yourselves.

>> Sure. AMA supports the objectives of the rule. We see some challenges with the implementation but physicians are strong supports of patient privacy and AMA welcomes the heightened protections around reproductive healthcare. To protect patients and their physicians who are often the ones caught in the middle when people with efforts to use peoples' sensitive health information against them or their medical provider.

So we embrace the objectives of the goal. But there are challenges. It's going to be a significant implementation lift for physicians, 238 days from today.

These systems need to be up and running.

It's quite a lift.

And we look forward to more guidance from OCR about the implementation strategies. And we want to make sure especially rural providers and those with fewer resources have what they need to launch this successfully. If you've ever done an implementation, you know the more you can get right the first time, the smoother it goes, the quicker you see the objectives that we all want to see happen with this rule.

>> ANDY CRAWFORD: Erin.

>> Yeah, thank you so much for having me. You know, I think it's really exciting to be here today to shine a spotlight on these new protections. We are -- we applaud the Administration action to expand protection for reproductive healthcare information in response to the chaos caused by Dobbs. We continue to see and to feel every day the ways in which that decision has undermined access to basic healthcare.

And because we live in this information or data age, we'll are understandably increasingly worried about their privacy and whether or not whether and how their information can be weaponized against them.

And this is not an unfounded fear. Women have been subject to criminalization for pregnancy and abortion for a long time.

Particularly Black women and women of color have before this were more likely to be subject of investigations and proceedings related to lawful reproductive healthcare and we also know those Communities of Color are more likely to experience inequities

in both access to and outcomes of care.

So I think you know criminalizing -- we know that criminalizing pregnant people deepens mistrust and exacerbates these health inequities so this is a really important and exciting first step and we're looking forward to working with the Administration and all of our allies to continue the momentum.

>> ANDY CRAWFORD: Alice.

>> Thank you and thanks also for having me.

My topline take is going to be a little different because I don't work for an advocacy organization I work for a law firm so I think what my clients think yet I will say that in the wake of the Dobbs decision, Manatt, the firm for which I worked formed a reproductive health Working Group where we've really been focused on what does this mean what does Dobbs mean for our culture but really more specifically what does it mean for our clients what does it mean for states what does it mean for interaction with HIPAA and FTC rules as we heard about a little bit. So I do think the clarity of this rule is enormously helpful. Whether or not it's the final word, probably it is not.

But it is always very helpful and we get anything from OCR this was such a privilege to be in the room with the Director on how the agency sees this rule interacting with state law, how it sees the new rule interacting with other previous HIPAA updates, FTC updates. So we will be eagerly looking for further guidance, all of the videos, all of the implementation guidance. Because the more that we hear from OCR, whether it's topline goals of the rule, why the rule was published, I thought that was very interesting or read in the preamble and hear in person.

And then once we see how it's rolled out with respect to implementation what we can do about addressing implementation challenges and concerns that arise.

>> ANDY CRAWFORD: Thank you, everybody, I think those are great first insights. Let's take a little deeper dive. Part of what Alex and Director Fontes Rainer talked a lot about was that essential element of trust between a patient and a provider and how privacy plays such an essential role in establishing that trust. And maintaining that trust.

So I'm going to start with Erin and Lisa with this one, you know, let's talk a little more about how you see the new rule bolstering that essential trust between a patient and provider.

>> Sure I'm happy to start and I think given the context is reproductive healthcare it's important to have our history in mind. And the fact of the matter is that again, Black

women, women of color, have long been subject to forced sterilization. To abusive gynecological practices. To a pattern of racism and mistreatment that continues today and is most starkly apparent in our maternal health crisis.

And so there are communities for whom that trust with the healthcare system is, you know, may have never existed. And so I think it's really important to have that in mind as you're thinking about whether and how this rule will bolster trust so again I think this is a really important step, you know, again, I think we'll talk a lot about this how it will all come down to implementation and enforcement. Director Fontes Rainer talked about some of the requirements, the change to the notice of privacy practices.

I think those are really important steps and I think they have to be accompanied by ongoing conversations with -- between providers and patients. That's really where those relationships are. That's where the trust is built. So making sure that providers and patients understand their rights and their responsibilities under these new requirements is going to be important.

>> ANDY CRAWFORD: Lisa?

>> Yeah, I would say patients trust their physicians right now they have lost faith in the system we use for sharing health information. In the current system, the same information, the same reproductive healthcare information, that could land you in jail or cause your children to be taken away. It has the same level of privacy protection as your cholesterol number or your blood type. There are no tiers, it's all treated the same.

And this new rule addresses that. So it can help to protect both patients and medical providers. And over time with outreach and education, it can help to restore the trust that people have in the system to know that they are lawfully obtained reproductive healthcare is truly private it won't be shared with law enforcement or legal authorities unless they attest it won't be used against the patient, the provider or anyone who helped them or attempted to help them. That's very important for both the patients and providers.

>> ANDY CRAWFORD: Absolutely. So Alice, let's turn to you for another question. We heard a lot earlier about how the Dobbs decision just kind of changed everything and reset a lot and opened up a lot of new avenues where reproductive health information could be used in ways that just weren't possible prior to Dobbs.

Why don't you talk a little bit about how this new rule seeks to kind of close some of those gaps and also you mentioned earlier we kind of have seen how the states are

reacting to this, too, so if you can touch a little bit more on how states are kind of on -- kind of on both sides of this have kind of approached up to the rule and the rule itself.

>> Sure, one of the benefits that state-level legislators have is they can move much more quickly and be much more nimble than the Federal Government.

The April 2023 Proposed Rule from OCR and then the April 2024 Final Rule it's actually very fast moving. They responded very quickly. Dobbs is also several years old at this point the states on the other hand in the wake of Dobbs almost all of them reacted almost immediately. Some of those states took action that was now legal to restrict access to and provision of abortion and others put into effect what we refer to as shield laws.

As of a few months ago, it may have changed even since then because it changes so quickly, 15 states and the District of Columbia have passed what are called shield laws, which protect the rights of abortion seekers and providers in their own state.

And specifically protect people who come even from out of state to receive or obtain lawful care within their state where abortion is legal.

Some of those shield laws have come in the form of Executive Order. Again, something that the state governors have access to. Some of them have come in the form of updating the state codes and regulations themselves.

But this HIPAA rule when I was reading it just made me think about abortion shield laws because one of the central tenets of these state laws is to protect recipients or providers of lawful care in their state from out -- from the disclosure of information from out-of-state investigations, imposition of liability. Sort of extradition, all of these things that we are all worried about given the patchwork of laws that we have in this state in the wake of Dobbs. The shield laws are really designed to protect those recipients of care in their state from those.

The state shield laws also contain a number of protections for providers, they can't be subject to professional repercussions whether that's in the form of licensure or malpractice insurance premiums.

And some of them go so far as to protect actual residents from specific disclosure of identifiable information related to reproductive health or their identity of them in receiving that care.

Some of them are broad and apply to gender-affirming care and all reproductive health services some are more specific to abortion all of that to say that this Final Rule

is like those. But not as deep not as nuanced, not as specific they really take existing HIPAA permissions for disclosure and switch those to either having a prohibition for certain purposes, purpose-based restriction as we've been calling it.

And a focus on presumption of lawfulness. Which again, the states have access to. Because they know in their own states whether it's lawful or unlawful.

That was a very long and boring answer to the question.

But the point is is that this is in line with state laws. But it doesn't go as far.

So the sort of gaps that Lisa and Erin are talking about, this law does not -- is not able to and does not accomplish that.

>> ANDY CRAWFORD: Understood. I didn't think it was that boring.

>> Oh, thanks.

>> ANDY CRAWFORD: So let's unpack a little more take a next dive deeper into certain elements of the rules and I think Alex and Director Fontes Rainer talked about the presumption that the rule may instill you just talked about a little bit more but there's also an attestation component that an entity requesting this data now has to attest it's not being used for a prohibited purpose.

I'll open this up to everybody but you know, feel free, whoever, let's talk about kind of why that attestation is important.

What elements are included within it. And you know why it's really necessary for this rule to function.

>> Sure, yeah, it is an important component of the rule. And it sounds complicated. There are six required elements of a valid attestation. I think of it as 3-2-1. 3 names, 2 statements and a signature. The name of the patient, the name of the discloser, the name of the recipient. A statement that it won't be used for a prohibited purpose, won't be used against the patient the provider or anyone who tried to help them access reproductive healthcare this all pertains to lawful reproductive healthcare second statement this is important, too, that HIPAA penalties attach to anyone who seeks to abuse this process. And also who would redisclose and then the signature.

So it's implementable. It will take redesigned workflows. It was a scramble when HIPAA first came out to everyone crafted a notice of privacy practices, everybody crafted a business associate agreement.

But we're happy to see some skin in the game on both sides of the information sharing equation because usually the penalties and compliance obligations fall on the

medical provider because they are the ones that are covered entities under HIPAA but in this case there are some significant penalties that attach.

So we're pleased to see that. And with the presumption I'll just quickly say it sounds complicated we don't want doctors to have to go through a difficult analysis but if you think about it the presumption applies to reproductive healthcare that was provided by someone else. So as they reviewed, you don't know so you make a presumption. Or an assumption. When you're the one providing -- when you are the one who provided the healthcare that is in the records being sought you don't have to make an assumption. You know what you did.

So that clarifies I think a little bit for me like it really makes sense to apply it to other providers but not for the provider who provided the care.

>> And I would say from the National Partnership's perspective as far as the attestation requirement goes we had hoped for a stronger mechanism to guard against bad faith actors we know they are out there but we understand why the Administration thought -- why and how the Administration finalized its requirements.

And I think to Lisa's point about the difficulties of implementation, I also sympathize with the concerns around administrative burden and there are a lot of documentation requirements in healthcare. And especially when it comes to health information sharing.

And we think that this rule strikes the appropriate balance for protecting peoples' information. Who are you know seeking reproductive healthcare. And as we have discussed, it also provides that much-needed clarity for providers.

You know, we have partners at Pregnancy Justice who have found that one of the leading drivers of criminalization regarding pregnancy status or outcomes is providers feeling appreciated to report to law enforcement. So we're hopeful that this rule will provide that clarity, that assurance that they don't need to worry about that.

>> ANDY CRAWFORD: Alice I don't know if you want to weigh in.

>> I would only add in from the legal perspective there's a lot of discussion in the Final Rule about how can a provider know when it is appropriate to rely on an attestation so to me I was very appreciative from you know the provider-client side of how much time and thought OCR went into this balancing test as you say, understanding that it might be -- that it is one more administrative layer of work upon them. But that they want to make sure that the providers feel comfortable in saying, I got an attestation and I'm going to rely on it and I feel good about that. There's a culture

of fear in a number of places in the healthcare system, not just on the patient side of obtaining care which is also addressed in the rule but of providers not knowing what they have to share, what they can't share, what they should be sharing. So any time there's specificity in what you should share under what circumstances and how you know whether or not to -- whether or not the circumstances are appropriate, I think is much appreciated.

>> ANDY CRAWFORD: Excellent.

Let's move on to kind of next steps now. You all represent different stakeholders, different entities within the Division of Healthcare. We heard from OCR Director Fontes Rainer that a big push for OCR moving forward is getting the word out about the rule why don't you talk about how each of your organizations are approaching that. What next steps you see for the immediate future and potentially longer down the road.

>> Yeah, I would say this is when the work starts for physicians. To get all these workflows up and running by late December.

We definitely are looking for more specific guidance on aspects of the rule just to implement it you know as seamlessly as possible, for example, what are the limits of requiring an attestation before you run afoul of the information blocking rules? There's been a lot for physicians to implement and digest. There was HIPAA which is some time ago and then more recently okay HIPAA said don't share patient information but here are six scenarios where you can.

Information blocking rules said you know there's six scenarios instead of you can you must.

Unless you fit another set of exceptions. So layering this on top. It's going to take some intensive resources, education and especially for our smaller and rural providers.

So we look forward to seeing more guidance on the specifics. And I'm sorry; our member channels. We have a lot. And we put out an advocacy update every other week. Mailing goes out to the House of Medicine to the state specialty -- state medical societies and the specialty organizations.

We have a robust social media presence and of course the AMA website.

>> ANDY CRAWFORD: Erin.

>> Yeah, I think I'll start by focusing a little on whether we are eager to work with the Administration and stakeholders going forward.

Again, I think we fully understand and appreciate why the Administration limited

these protections to lawful reproductive healthcare.

But the fact of the matter is that Dobbs and anti-abortion politicians are making all kinds of reproductive healthcare from telemedicine abortion to emergency care for pregnant women illegal or legally ambiguous. And it's sort of just speaks to the confusion and the chaos that you were describing with this patchwork of laws, Alice. And so you know we are concerned that there will be some significant portion of reproductive healthcare that falls outside of these protections. And those individuals not only need that care but deserve to have their privacy protected, as well. So I think this speaks to some of the larger gaps in our health data and just data ecosystem that we need to fill.

You know, we -- Director Fontes Rainer talked about the limits of PHI. And we know you know in addition to providing care -- protections for more care, we also need to protect more data. There is so much information that's either health specific, whether it's you know pregnancy or menstrual tracking apps or location data that can be used to draw the same conclusions about the reproductive healthcare that an individual is accessing as PHI. And so we're really looking forward to again just working with everybody on strengthening privacy protections overall.

I would say in terms of the role that we play as advocates to get the word out about this rule, definitely working with a lot of our partner organizations, Planned Parenthood and others who have more direct contact with patients on the ground. But I think to Lisa's point about the confusion and how changes to HIPAA and how it will interact with information blocking, I think one of the biggest roles we can play is really just again shining the spotlight on this change. Making sure that people are aware of it.

I appreciate the desire to ensure and educate patients and consumers about their rights and responsibilities.

As a patient advocate, you know, when you are half naked in a paper gown, you know, Director Fontes Rainer talked about that imbalance that exists. And I want us to be mindful about how much we are putting on patients who are already navigating an incredibly difficult situation. A complex turbulent political environment.

To then put the onus on them to be reporting violations of their HIPAA rights. So doing what we can to make sure that that isn't necessary in the first place.

>> And we at Manatt volunteer to take on the job of explaining the Venn diagram of information blocking. Interoperability. HIPAA. And FTC. And then a subset of state

laws I feel job security. But it is complicated. And especially when you have laws like this new HIPAA rule that says here is when you can't or how you can't share information and other regulations like information blocking that say here is how you have to, it can be confusing. So after you sign up for the OCR newsletter and the AMA newsletter and the National Partnership newsletter Manatt Health does our best to synthesize that landscape.

>> ANDY CRAWFORD: Great before we pivot to questions and for folks in the room and online remember submit questions if you have them we're happy to answer them. Before we get to questions would love to go down one more time and final thoughts before we pivot to questions, final reactions, takeaways.

>> I would like to echo what Erin said about the biggest gap that I see is the health apps. Sometimes they are called health adjacent data and again everyone assumes my health information is protected by HIPAA. But these app developers, the app companies, they have nothing -- they are not covered entities they are untouched by HIPAA there's no minimum standard for their privacy policy. And people don't know that. And the FTC has I think done a commendable job with the tools they have in recent years but they usually can't step in until something really bad has happened. So I think some regulatory level setting in that space would be helpful. And again we look forward to working with OCR and our stakeholder partners to get the word out and to make this -- we all want this to work and for it to be workable there needs to be clarity. Ambiguity is friction in the compliance context so we need to get these workflows going and be in good communication about all the issues that need to be addressed.

>> ANDY CRAWFORD: I'm going to resist the urge to take us down the path of nonHIPAA covered health privacy we could fill up a whole other hour here but I'm going to resist. So Alice, I know we could just break out another --

>> Another plug for the consumer framework. But you know to your point, Andy, there actually has been a lot of activity in the privacy space on the Federal level recently. I know that there are many who think that there hasn't been enough. I know there are many who are still praying every single night for comprehensive Federal privacy legislation but when you think about what the FTC has done in the health app or nonHIPAA covered health space in the last several years and what HHS and OCR have done and what CMS has done, it's actually been quite a lot of activity. And the Administration really seems to be on it. Director Fontes Rainer was saying earlier that

there's some aspects of this that are nonpartisan and that's absolutely true patient access to data and patient privacy are not -- abortion of course is and reproductive health is and overall access to privacy data is not so I think we'll probably just see more and more. And we should be heartened that privacy is such a hot topic these days.

>> And I think I would just add you know the National Partnership is ready and standing by to participate in the shared responsibility of education and awareness raising. Because clearly there's a lot going on.

There are a lot of people to inform so we want to assist with Manatt and everyone else to release guidance and release maybe suggested scripts to have conversations with patients. In addition to those documentation requirements we think will be helpful.

>> ANDY CRAWFORD: Okay we have a couple of minutes for questions so we'll just start I'm not going to profess to know the answer to all of these I don't want to put anybody on the spot to as well but let's give it a shot but some folks are asking if we expect the new rule to spark litigation. Specifically from state AGs. As an addendum to that one what other ways do we think courts will play a role in this new rule we have seen courts playing in this.

>> Yes.

>> ANDY CRAWFORD: Are there other ways you see courts getting involved besides just direct challenges to the rule?

>> I don't know that they can get involved without direct challenges to the rule but I think it's a matter of days, weeks, before we start seeing those.

>> And I think that State Attorney Generals collectively already sued on the Proposed Rule. I mean it's a contentious space as we all know. And I just want to say, too, I expect to hear a little more about gender-affirming care because that was one of the things that AMA asked for that's been used some would say weaponized against patients and their care providers and I thought it was well crafted. In the Final Rule they have expanded the definition of reproductive healthcare if you do a word search there's not one instance of the word gender. But there's lots of encouragement to construe gender affirming -- I mean reproductive healthcare broadly. And if you look at the text of the definition, there's also a hint in Footnote 163 about marginalized communities and that's who we're seeking to protect with this, vulnerable people so that's very encouraging.

>> ANDY CRAWFORD: I agree that's one of the things CDT called for in our

comments as well the broad definition to include gender affirming care so some more clarity on this is always welcome I think we have time for one more so again I don't want to put Alice on the spot but I'll throw this at you first but folks are asking how does the new rule interact with various state laws like for instance the Washington My Health My Data Act.

>> I'm available for legal consultations at any point I would just like to say. I'll answer it fairly broad because the Washington My Health My Data Act is very specific but as everyone know Federal law preempts state law but also Federal law is a floor and states can layer on more restrictive policies and requirements on top of that.

So if there is a state that would say that the uses and disclosures that the new rule prohibits are actually permissible, that would not fly anymore.

But if the state wanted to impose additional protections or additional prohibited purposes or a different -- additional for example attestation requirements, expand the prohibitions. In the new HIPAA rule, they would be able to do that.

I can't off the top of my head think about what the permissions and restrictions in the Washington My Health My Data Act are that might be either in concert with or in conflict with HIPAA.

But I will say that more and more states are expanding their mini GDPRs their state and privacy laws to be specific to health data we have seen it in Washington and several other states and if you look at the map at where such legislation is proposed it's almost all of them. So this task of analyzing the state health data specific privacy laws sort of outside their little mini HIPAA laws is going to just become more and more important. And the interaction with the HIPAA Final Rule will be a component of all of that state-level analysis.

>> ANDY CRAWFORD: Great. I don't know if -- great.

I think that is going to conclude our webinar and Fireside Chat today. I just want to take the opportunity to thank everybody to our panelists, Lisa, Erin and Alice, thank you so much.

For doing this. And not only doing this but doing it on somewhat short notice so thank you, thank you, thank you, I thought today's session was fantastic a huge thank you to HHS. OCR. Director Fontes Rainer and her staff.

Thank you to the CDT staff that helped put this together. And thanks everybody for joining us and for participating.

Yeah. I hope everybody has a great rest of your afternoon.