



HL INFLUENCERS: DIGITAL TRANSFORMATION TRANSCRIPT

MELISSA BIANCHI
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| Leo von Gerlach | Hello everybody and welcome to another edition of The Influencers, our podcast conversation on digital transformation and law. I'm Leo von Gerlach and with me today are my Hogan Lovells partners, Melissa Bianchi and Cybil Roehrenbeck. Both are located in our Washington, DC office and each of them lead one of the most important aspects of the Hogan Lovells healthcare practice. Melissa leads our global digital health initiative, and Sybil is the co-head for our healthcare lobbying practice. So that puts them into an ideal position to dive deep into digital health and related AI initiatives by the US government and relevant stakeholders in the healthcare industry in the US. With that, Melissa, Sybil, welcome to the show. |
| Melissa Bianchi | Hi Leo. Thanks for having us. |
| Cybil Roehrenbeck | Great to be here. Thanks. |
| Leo von Gerlach | Let's dive right into it. We have a fairly challenging and difficult topic ahead of us and to get started, Cybil, perhaps you give us an idea where U.S. federal government stands at the moment with their AI initiatives, and then how that fits into the healthcare space, and how these it's general AI initiatives, more broadly, interact with what we see on the healthcare front? |
| Cybil Roehrenbeck | Really, it's all systems go from a US federal perspective on AI. One of the early executive orders that we saw come from President Trump had to do with empowering AI developers and users of AI to really innovate. We want to be the best in the globe in this area from a US perspective and so I think that there's a recognition that many other countries, many other nations, have really invested a lot in their AI development and the White House would like to get there and exceed those efforts. We also saw an immediate pullback of an executive order that President Biden had issued, which had a lot of emphasis on mitigating bias, guardrails, and protections. The Trump executive order on AI is much more around enabling AI developers to move forward unencumbered. And then we've seen some concrete actions after that first. Most recently there was a White House action plan that came out from the Office of Science and Technology Policy at the White House that was sort of industry agnostic, but it talked about priorities for AI and a number of different areas, including pulling back existing regulations that could potentially encumber AI or not. Didn't make sense in the new context |

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| | <p>of AI systems, as well as education around the use of AI. So we are seeing a lot of that now trickle down to the departments and executive agencies and seeing implementation around what can the federal government do to really help companies innovate in this area and how can they act as a test bed really in this space. The last thing I'd say is that to do those things you need money. So one of the big things that we also saw as part of the one Big Beautiful Bill Act or the Federal Reconciliation Bill, which extended the tax cuts and did a number of other very large federal initiatives. We saw a lot of funding there for artificial intelligence and a lot of it is in terms of the use of AI inside the agencies. So agencies trying to become more efficient and think about legacy systems and how they can be updated or changed out for systems that incorporate AI, but also how we can see AI really pushed out and enabled in the private sector as well for healthcare, interestingly, there was a huge fight in that bill around Medicaid payments. But there was a large fund that was authorized and appropriated for rural health and for rural health systems, and a key part of that, very interestingly, in the statute itself, there was a focus on the use of AI and digital health in rural communities. So we're seeing a ton of activity in this space. We've had two Congressional hearings just in the last two weeks to talk about how the federal government can help AI innovation and we expect a lot more in the near future.</p> |
| Leo von Gerlach | <p>So all right, I understand there is on a general level, the AI Summit and the winning AI race theme and the AI action plan, and that is now to be underpinned in the healthcare space. And if I get this right, there was recently an event Make Health Tech Great Again. In Washington DC, organized by the White House and the centers for Medicare and Medicaid Services. So, Melissa, can you just give us an idea what this healthcare specific event and initiative is all about?</p> |
| Melissa Bianchi | <p>Sure. Well, why don't I start with that? I mean, as you said, there's a Make Health Tech Great Again initiative. And I think it does fit into the broader ecosystem. And I think that AI is really going to be a focus of this newer initiative. So to step back the Department of Health and Human Services and one of its agencies, the centers for Medicare and Medicaid Services, launched a new health tech initiative. It's really intended to be a digital health technology ecosystem, and it's a partnership between the government, between HHS and CMS and the private sector. And there are a number of goals built into this health tech initiative, but at its core, it's to give patients greater access to their own medical information, and that's going to happen through a standardized health data exchange. And part of this ecosystem is going to focus on personalized digital tools for patients. And that's going to include mobile apps that use AI for things like disease management or for scheduling of doctor's appointments. So a key part of this initiative is also disease management, starting with the focus and the diabetes and obesity space and as part of that, CMS really contemplates that there will be digital assistants that are going to engage with patients and using AI and so I think we'll see AI as a key component of many of the tools that the agency is contemplating not only for patients but also for healthcare providers and I</p> |

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| | think that fits into the broader part that Cybil was talking about at the AI action plan, which focuses in part on removing barriers to adoption and also supporting wide use of AI. I think it's really a natural next step and component of the AI action plan at a specific agency level. |
| Leo von Gerlach | And just sticking with those components, do I get this right that I mean adding that them all up together somehow forms this CMS interoperability framework and that there is a cohesive concept meant to underpin all the different points you just mentioned? |
| Melissa Bianchi | Well, there is a part of this health tech initiative. There is this interoperability framework that CMS is creating and it really builds on 15 or more years of focus from the agency on interoperability in the healthcare world. We've come from such a paper based and segmented healthcare world and you know more than 15 years ago Congress passed the High Tech Act which really took a big step in making all of our healthcare information more interoperable, more interconnected and really created a set of standards that are aimed at providing patients with better access to their information. You should be able to get a copy of your medical information. You should be able to share it with others. Your doctor should be able to share it readily with each other. And so, you know, we're, you know, more than a decade into the creation of standards for doing that and for improving quality and the creation of exchanges of health information that are really designed to make your medical information available to you wherever you receive care. And there been a number of laws, the 20th Century Cures Act and other's in the interim that have really set standards. Some components are to penalize entities that engage in what's called information blocking that make that that exchange of information harder. So that's the stick and there's the carrot to establish improved framework for information exchange and healthcare. So this is really the next step in that evolution to make sure that private entities that offer mobile apps that patients want to take advantage of to improve their healthcare have the ability to get their medical information into those apps and use it for improving their overall wellness and care, and that health systems also can do that. So it's part of a broader effort in making the exchange of health information more seamless so that your doctors have the actual current information about you to provide your care and that you can use your own information to self direct some of that. |
| Leo von Gerlach | So that makes a lot of sense to me. Sounds like making data flow more easily, making access to data better, improving transparency and Cybil, that then I would assume translate into some very specific action points where the experience of the individual patients should be improved. I understand that there are things like speed up, the patient experience or conversational AI assistance, certain diabetes tools, certain obesity tools. Could you talk us through them? |
| Cybil Roehrenbeck | Sure, this announcement was classic Trump White House announcement, even though it was really focused at HHS. You had a number of these companies coming, proffering to work on something that has been a very |

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| | <p>difficult that for HHS to crack for many years, as Melissa knows, better than I do, interoperability. So come to the table, say that you'll work voluntarily on interoperability, and you know, we can help enable your tools getting into the hands of patients. It's it was a much more dynamic, creative way to get companies to the table, but I also think there's a piece of this of allowing not just the much larger companies and maybe some of the legacy, you know, health information companies, but others enter the market by putting new emphasis around interoperability, so that even for some of the small startups, they're not swallowed up by some of the legacy systems. So there were a lot of elements just in terms of policy and politics that were at play here that were super interesting to watch. In terms of what we might see, I think they really are going to emphasize and they did emphasize in this announcement tools that relate to some of the conditions that they've prioritized. So cardiac disease, diabetes and they want to see things like wearables that can help people track their heart rate, better understand their glucose levels, track their exercise regimen. CMS and doctor Oz I think have really tried to think creatively about some of these things, but I'm not sure that there's cohesion throughout all the various parts of the department in terms of how they'll move forward on some of these apps. Some of them require FDA authorization, others don't. And as those issues continue to come up at HHS, it'll be interesting to see how this Make Health Tech Great Again Initiative is allowed to move forward. I think it it's something that we would love to see more of and many more companies would like to participate in even that the long, long list that they announced in the original announcement.</p> |
| Leo von Gerlach | <p>So among all the regulatory challenges you just mentioned around those new tools, let me just follow up on the interoperability of data that seems to be so overriding really important and the legal concern that come with it and one is certainly always privacy concerns, HIPAA Compliance, Data Act compliance. Where do we stand at this crossroad between privacy concerns, on the one hand, and this desire to make data more interoperable for these tools?</p> |
| Melissa Bianchi | <p>Yeah. So I'll take that one. I think that certainly there's been a lot of focus on privacy issues around this initiative. In the United States, we don't have a single privacy law. So HIPAA is the law that covers healthcare providers and health plans and the goal of this initiative is really to put patients a little bit on the driver's seat with respect to their own information and to use apps might be on their phone that they could use to manage weight loss, for example. And these are all already, you know, apps in the ecosystem and I'm sure more will be developed, but those entities and some of the tech companies or their companies developing these specific mobile apps, they aren't necessarily covered by HIPAA and in many cases they aren't. And so if I'm a patient and I wanna get a copy of my medical records and I wanna share it with my Wellness app, I have the right to do that and this initiative is designed to make that even easier that already happens today. This is really trying to make this more widespread and to create more tools for patients to access their information and to use it for their own self-directed</p> |

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| | <p>care. But anytime you do that, you're taking data from this HIPAA ecosystem and you get into a different ecosystem, which is really a consumer space and anytime you are moving data from one legal framework to another, there are potential risks in that and moving data from the HIPAA space to the non-HIPAA space and certainly that can be done and it is done pretty commonly today, but it does pose potential risks and so I think one of the questions is to what extent are patients going to be asked to understand that they're moving their data into a space that has different protections? How much do patients need to understand how much will they understand? Will they understand the consent framework and the choices that they're making with respect to the collection and use of their medical information? So again, it's not new, but I think the goal here is for that to happen on a broader scale and the framework is very high level right now. And you know, it's a series of bullet points and there is a lot of existing framework, you know that's been in effect for a while but building that out in a way that ensures data protection principles remain in place is going to be important that patients understand the choices that they give meaningful consents and that there are security features built into that, that's all contemplated in the framework. And so the devil will be in the details as it always is as to how that gets built out in a way that maximizes interoperability while also maximizing the privacy and security protections on data as they move from the HIPAA world to the consumer health privacy world, which in in this country is largely governed by state law and some by the Federal Trade Commission, as well as an overall framework. So that'll be part of the challenge. I think it's certainly something people are acknowledging and have some experience already working with.</p> |
| Leo von Gerlach | <p>Melissa, that's incredible. Interesting. So these tools create data spaces and then, of course, it's the question for the patient to what extent his privacy is affected, but then it's not only the patient, but it's also all the other stakeholders, the providers, the platform operators, the payment providers, what due diligence questions do they need to ask themselves when considering to participate in such a data space and making use of one of those tools?</p> |
| Melissa Bianchi | <p>Well, I think there are a number of considerations. I mean, there is a lot of information in those bullet points in the framework and it is again building on many years of good work at the agency to set up in our operability standards. So I think really understanding what those standards are, you know, focusing on what the framework as it exists now, this newer framework and this next step really and an interoperability initiative looks like and how if you are a company that has a mobile app, there are existing standards really that come out of the 21st century cures and other interoperability standards. This will take it to that next step and anticipating and understanding that next step and really building your ability as a tech company to make that connection to have API's and to build API's that really can interface appropriately with electronic health records and other sources</p> |

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| | <p>of health data. Really readying yourself to move that data when the patient makes that choice to your ecosystem, to your app is going to be key.</p> |
| Leo von Gerlach | <p>So Melissa. Thank you. I mean, now I think we have a good understanding of those regulatory concerns that you have to observe when participating in whatever role. But there's also the side of benefits and Cybil, perhaps you can explain what patients and other beneficiaries should look out for when it comes to really making the most of those envisage tools.</p> |
| Cybil Roehrenbeck | <p>I think in terms of benefits, there are many, many benefits. We are way behind in terms of integration of technology into healthcare. If you think about many of the other things that you do throughout your day, tech is really part of the way that we work, the way that we interact with our friends, the way that we interact with our family. Healthcare, not so much. It might be a clunky platform that you come on to, to look at your test results once a quarter and that's about it. And so we have a long way to go, but I think the reason why it's been so delayed is because this is people's health we're talking about and safety. And there are a lot of considerations. So one thing that many stakeholders, including the AI healthcare coalition that that we lead has been working on is this idea of a nutrition label for AI. So much like you'd have a nutrition label for a box of crackers you pick up in the grocery store for a patient and for provider to be able to look and quickly discern the sensitivity, specificity, whether the AI is actually going to be helpful to them or not. But of course there shouldn't be a burden on patients necessarily to be tracking those things. I think for AI medical services we will see. I mean already there are a number of rules on the books through HHS for Medicare beneficiaries and Medicaid beneficiaries, rules where the physician is required to go in and kind of look at what actually the AI tool does, how helpful it could be or not. See in terms of diagnosis or designing a therapy program for the patient and so a lot of this will be reliant on what the health systems integrate and what the medical practices integrate. We're also seeing a lot of activity in the States and so just today, I think there's a bill sent over in California to the governor's desk around AI chat boxes that could have implications for medical providers. We've seen changes in many different medical licensure laws in the States and so that will continue and some of that will have some of these guardrails that folks I think have been working on. One last thing I'll mention, Congress on the federal level did consider an AI moratorium that would pause the state legislation while we came up with a federal structure for some of the guardrails that you mentioned, Leo, and that did not pass as part of the one big beautiful Bill Act. But my sense is that there will be additional attempts at getting that pushed forward in perhaps end of year legislation this year, so that tension between the federal desire, I think to try to see these things move forward and get quickly into the hands of patients, you know once reviewed for safety and efficacy and some of the state laws that are taking a more conservative approach. We'll continue to see that play out over the coming months and years.</p> |

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| Melissa Bianchi | <p>I might just add to that, Leo, in terms of your questions around who will benefit here. You know, I think that the involvement of the private sector and some of these initiatives coming out of the agencies right now that we've been talking about. I think involvement of the private sector in such a concrete way creates a real opportunity for companies, and I think that's true for health systems, for our tech companies, wellness companies, companies and all sorts of disease states and for health plans. You know, I think as Cybil said at the outset, there were there were more than 60 companies at the table, at the press release when this new technology initiative was announced. And those are the early adopters. Those are the companies that have signed a pledge and agreed to implement the framework, the details of which are actively being developed. And so I think for those companies, there's an immediate short term job, which is to, you know, meet the commitment they've made and to adopt this framework, which is going to be a bit in real time as the framework is implemented and built out and I think for other companies there's going to be an opportunity as well and figuring out how to come to the table if you weren't part of that list of early adopters. How do you come to the table and engage? Because I think there are real opportunities for a whole range of stakeholders in the healthcare ecosystem. Being ready for that and really understanding that is going to be important for companies in a variety of seats at the table here.</p> |
| Leo von Gerlach | <p>That sounds like a really exciting dynamic. I mean, Cybil and you, Melissa, have just talked about the benefits specifically for patient. Also the excitement that is out there in industries and those participating. And on the other side, there's still so many regulatory challenges. There are these differences among state and federal laws and so many other. If you take that all together and talk to a given stakeholder from industry, what would your best advice be like just do this now if you want to embark on to this exciting journey?</p> |
| Melissa Bianchi | <p>Well, I would say start by really diving into the information available about the framework now and figure out how you as a company can fit into that and what the opportunities are for your business, for your platform, for the patients you serve. How are you going to be part of this initiative as it moves forward? Really map what you're doing to this framework and figure out what your role is and how to start building towards that. There are a lot of existing, you know, rules on the table that you can start building toward if you haven't already. But understanding the opportunity here I think that's really the key next step for a lot of companies and other stakeholders, figuring out how to fit in and how to be ready to even if you're not an early adopter, how to be ready to be in that next stage of adopters if it makes sense from a business perspective to join on.</p> |
| Leo von Gerlach | <p>That's really, really, really good advice. So thank you for that and Cybil, Melissa, thank you for all your terrific insights. It's a fantastic. It's a very, very exciting topic. Surely we will hear more about it very soon. But for now, thank you for participating and thank you everybody for listening. Join us for</p> |

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| | the next session of The Influencers, which will be coming up soon. Till then, take care goodbye. |
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