[Music]

Marianne O'Hare: Welcome to Conversations on Health Care. This week we welcome Micky Tripathi, National Coordinator for Health IT at the Department of Health and Human Services on a new era for patients who can now digitally access and control all of their health data.

Dr. Micky Tripathi So that's what they have and that's what the, all of these rules build upon is the patient's ability to express their right of access to say I want all of my records.

Marianne O'Hare: Lori Robertson joins us from FactCheck.org and we end with a bright idea improving health and wellbeing in everyday lives. Now, here are your hosts, Mark Masselli and Margaret Flinter.

[**Music**]

Mark Masselli: You may not have known it but October 6th of this year was Liberation Day. That's Data Liberation Day because that was the day Americans officially had full access to their health data, starting on October 6th health care organizations were legally required to give patients unrestricted access to their full health records in digital format.

Margaret Flinter: Joining us today is to talk about these new rules and other health IT and innovation issues is Micky Tripathi. He is the National Coordinator for Health IT at the U.S. Department of Health and Human Services.

Mark Masselli: Well, welcome, Micky to Conversations on Health Care.

Micky Tripathi: Thank you. Thanks for the opportunity to be here.

Mark Masselli: You know these are new Federal rules passed under the 21st Century Cures Act and as we know other government mandates and really billions of tax dollars have pushed forward the use of electronic health records, but on October 6th, patients really got access to what they wanted. Can you tell us more that?

Micky Tripathi: Yeah, the 21st Century Cures Act which was passed in 2016, you know so it's passed a long time ago, that was signed by President Obama that gives you a sense of how long ago it was perhaps with very strong bipartisan support, you know 98 senators, I think in an equal sort of a proportion on the house side support and of course Vice President Biden was you know very involved in it as well. And the rules that implemented the one piece that you're referring to which is related to what's called the information blocking, actually went into effect on

April 5th, 2021. So that was the date when provider organizations, certified technology developers and what are called health information networks were required to make available all electronically accessible information to not only patients but to other authorized parties. So, provider-to-provider exchange for example or to a payer or to a public health agency.

The reason October 6th is really important is that on April 5th of last year was when the rule went into effect and it said everyone needs to start doing this. But what we did is we said, let's phase this a little bit, because we know it's complicated. And so with the 1st Phase, what we said is, what you are required to minimally make available was kind of a minimum data set that we call the U.S. Core Data for Interoperability. And for those who feel like you don't know what that is, I assure you, you pretty much know what that is, because whenever you log into a patient portal, what you are actually seeing is basically defined by ONC regulations.

Then what we said is we will give the industry 18 months to adjust to this. But then 18 months later, and that was October 6th, it opened up to what's called Electronic Health Information which is what the 21st Century Cures Act called all electronically accessible information.

So I think as you said, it basically is all of your digital information that's required to be made available. That's you know basically the importance of October 6th. It really is a milestone day for sure.

Margaret Flinter: You know patients are often afraid and anxious I think about their health records, I don't think they felt they had much access to them back in the old days of paper records, either. But that such important information and you know it may impact whether they feel like they can change providers, if they don't know whether they can transfer medical records easily. Do you think this really opens up more options for patients to kind of take control of their healthcare, to switch providers or specialists or hospitals if they want to and what do we know from early experience about patient's willingness to engage in this process?

Micky Tripathi: Yeah, I mean it's still very early. You know people aren't really used to having this kind of access to their information in healthcare. You know we are a paper based world, people are just starting to get used to patient portals for example. And now as we start to move into the area of APIs as they are called Application Program Interfaces, you have more Apps

that are developing that you know allow people to download their records and bring them into their own hands, like the Apple Health Record for example.

But I think that is the sort of the hope, is that what this allows is a couple of things, one is that patients have the opportunity to be more directly involved in their care and one of the choices, they also want to be able to make and this affords them more the flexibility to do that, is to move from provider to provider for example, to not be tied to well I am going to stay here, because they have my records. This allows them the opportunity to do that.

But I will point out that all of our other rules do require that providers make that information available, provider to provider. And so that's a part of information blocking, is it if a patient says, I want to go over here to your competitor across town, that provider who you know you're leaving is under information blocking, they would be, you know that would be an information blocking violation for them to prevent that information for pulling to the other provider even if the patient wasn't in the middle of it.

Mark Masselli: You know Micky, I want to go back to your first answer where it seemed to me that there was a lot of intentionality in the design of the roll out here, gave everybody in the hospital and group practice area 18 months to sort of get ready, but I understand that some of those hospitals and practice groups are really pushing back and they are saying they need special consideration for their infrastructure not being ready for this new reality. How is ONC assisting these entities?

Micky Tripathi: Yeah, so first off, we certainly appreciate, you know, the concerns that they -- that they gave and we talked to those organizations on a regular basis. So, in terms of change being really hard, if you're a complex hospital system this isn't just about the information that's in your electronic health record system; in a complex, in a hospital system, you have what's in the electronic health record, but they have all sorts of other systems that live outside of electronic health record systems, some of which they may have bought, like 10 years ago. And it was never designed to make information available to like a patient coming in knocking on the door, saying, "I'd like that information."

And so the provider organization does need to deal with not only Epic or Cerner or Clinical Works and what they're able to make available. But now all of a sudden, it's like, well, that chemo dosing system that live outside of their systems, for

example, now they have to figure out, alright, how will that information be made available.

Mark Masselli: Remote monitoring devices at home.

Micky Tripathi: Absolutely, right, all of those things could now, you know, are now required to be made available as long as this is a part of what's defined as EHI. But I will say that this change has been coming for a long time, President Obama signed the law in 2016 and we --

Mark Masselli: He has got grey hair now.

Micky Tripathi: Right exactly yeah. And it got delayed like two or three times due to the pandemic, because we don't have the kind of interoperability that this rule is designed to direct upon. So at that point, we just said, you know what, we all have to move forward at this point. We appreciate change is hard, but now we all just need to get on with it

Margaret Flinter: Well, I was thinking, as you were saying that on a much smaller scale, remember the ICD-9 code to ICD-10.

Micky Tripathi: Oh yeah.

Margaret Flinter: And I think people asked for as many extensions to do that, as they have and it is just kind of the way it eventually –

Micky Tripathi: That's understandable.

Margaret Flinter: Of all the concerns that I would suspect we would hear is the question from the patients themselves or the consumers, if you will about "well, how are you protecting my personal medical records from landing where they ought not led?"People want their providers to have they want themselves to have them, everybody's familiar with signing electronically or with a pen, the HIPPA releases and who can have their records, but in this scenario, do you think patients will continue to feel that they actually own their own health data? Talk to us a little bit about that. And I wonder about new concerns about privacy of health records.

Micky Tripathi: Yeah, well, how much time do we have Margaret? So it's a huge, huge area that you're putting your finger on here. And one is just to clarify for everyone that in the United States, you actually don't own your medical record as an individual. So the idea of controlling it, you actually don't have the ability to fully control it. And that's just an artifact of the way we have built our medical, you know, legal medical record system. Provider organizations own the medical record itself, except in one

state, New Hampshire, where the patient does own their medical record. But one very important thing that patients have in the United States is they have a right of access to their records and that's what HIPAA grants them, a right of access to be able to show up at any provider organization, and say, “I want all of my records.” So that's what they have. And that's what you know, the all of these rules build upon is the patient's ability to express that right of access to say I want all of my records.

One of the things that I think from a privacy perspective, patients need to be very cognizant of is that HIPAA doesn't protect data outside of the stewardship of organizations that are regulated by HIPAA. So when your medical record information is in the hands of a hospital or a doctor or a health insurer, HIPAA absolutely covers that information. Alright, they're not allowed to sell the data, they're not allowed to make it available to others in an identified form without permission from the patient, you know, all of those things. But the minute that that information is in your hands as a patient, meaning you have downloaded that record onto your phone, let's say, that's now your responsibility and HIPAA no longer protects that.

So one of the things I like to keep reminding everyone and patients in particular, is you need to be extra vigilant, if you decide to download that information that's now available to you, and have it in your hands. And the thing that worries me is that Margaret or Mark, I'm going to guess that anytime you download an App on your phone, you will say, Okay, let's open the App and when it presents to you those user agreements, you click through it like ah, just yes, yes, yes, yes, yes, fine, just get me to the App, right? That's fine. I mean, do whatever you want in every other walk of life, but with your health information, don't do that. Pay close attention to what those privacy rules say, because that user agreement could literally say, we're just going to take your data and sell it in an identified forum and because that's no longer protected by HIPAA, there is nothing against the law.

So that's where the responsibility needs to come in. And just sorry, the last point is that if a patient is concerned about that, then what they can do is they can use the App that's provided to them by their provider, for example, like the MyChart App or a Healow App or Apps that are provided by the provider. Because if it's provided to you by your provider, it is covered by HIPAA, even though it's on your phone, you may not realize that it's actually not data on your phone and it's still protected

by HIPAA. And so that's what I would say is that people just need to be very vigilant about taking data into their own hands.

Mark Masselli: I want to sort of pull the thread health data are now among the most hacked data in the world. And I'm wondering how do we protect our health information, if more of it is going out to all of us? And then there's the other side of HIPAA patient information standards, are they up to the task in this new era or do they need to be re-imagined as we think about the issues around security?

Micky Tripathi: Yeah, so as you point out, if a HIPAA regulated entity, like a hospital or like a health insurer or a doctor's office, is required to follow the HIPAA Privacy Rule and the HIPAA Security Rule, which has all sorts of provisions in there for processes that you're required to have in place for encryption of data, for multifactor authentication, for any of those systems that we know, those aren't perfect, right, we all hear about the hacking into different healthcare organizations. But even with that they at least have the requirements related to the HIPAA Security Rule, which provides a pretty robust set of things that they're required to do.

Once your data is in the hands of just a vendor that is not covered by HIPAA, they're not required to follow the HIPAA Security Rule or the HIPAA Privacy Rule, because they're not governed by HIPAA. And so that's again the area where we need to have patient education right now and patient diligence and vigilance, diligence and vigilance around this, which is to say, when you have that App, there are many responsible companies who are looking really innovatively and creatively at developing services that can benefit from being able to take their data, to help them better manage diabetes, for example, or to help them with mental health or help them with management of pregnancy, for example, there are lots of great Apps out there, but the responsibility is now on you to say --

Mark Masselli: But we're still seeing these big hospitals being hacked all the time. And so are your security standards up to par in terms of the ever evolving cyber attacks that are going on?

Micky Tripathi: I think, you know, there's certainly more that, there's certainly more that can be done always. And the department is certainly looking at cyber security at large as well as specifically in the healthcare sector. But in general, I think one of the challenges that we all have is that cyber security is about people, process, and technology. The vast majority of

hacking events happen how through emails, phishing, right?

And so that's a bit of a challenge that you know, that it's not, it's not as if you can put a single technology into place, you got to be working all three of those angles to say that's how we have this kind of cyber security

Margaret Flinter: Well, Micky, I think you are in an incredible position to continue to move the needle forward on how electronic health information works to make things better for us. And certainly experts have said that one of the ways in which we found we were not well served during the pandemic was the fact that most health systems couldn't access data to spot Coronavirus trends. Are you in the administration targeting this as an area that you can learn from to God forbid we need it in the future for another pandemic or just to make things better in healthcare going forward?

Micky Tripathi: Yeah, absolutely. We are so we at ONC are doing a huge amount of work with the CDC, on the Data Modernization Initiative for anyone's interested if you look at, you know, just Google Data Modernization Initiative, you'll come to the CDC website, which is, you know, really rethinking the way we think about the availability of data through the public health data ecosystem, figuring out how we use Cloud infrastructure, to have much more efficient and effective mobilization of data for public health needs, that still protects sort of the privacy of the data from an individual level, as well as from a state level, because I think one of the things that we need to recognize in the U.S. is that public health just by the U.S. Constitution is actually a State authority. It's a 10th Amendment of the Constitution. It's one of the reserve powers that States have, which is public health.

So we're dealing with you know, 50, really 64 types of jurisdictions across the country. And so what we're working on with the CDC is how do you create infrastructure that can make that more efficient, right. We have lots of Cloud capabilities, I mean, you think about the you know what Netflix does on a day-to-day basis, right, using cloud infrastructure to make movies available to people all over the world, how do we take those kinds of technologies and say we can do that with public health that still allows every State to have the control that they want and need over their data according to their State laws and their State cultures and conventions, but allows us all to benefit from sharing of infrastructure and more interoperability across the system.

Mark Masselli: You know, Micky we've had several of your predecessors on

the show from the early days of the push for electronic health information, Dr. Farzad Mostashari and Aneesh Chopra. And they talked to us when the notion of easy flow of digital health data was just an aspirational goal. Maybe you can share with us what are some of the most dramatic advances to happen since that time and what do you see is on the horizon? Are we going to be in the Metaverse with health data at some point?

Micky Tripathi: Yeah, my simple mind has a hard time getting up to the level of the Metaverse, I'm thinking about how that's going to affect not only my life, but healthcare. But one of the things that I'm most excited about in taking this role at this time, is that I'm able to, you know, build on the great work that Farzad and Aneesh and Karen DeSalvo and Don Rucker and all my predecessors did in laying the foundation, right, because it was a ton of hard work, $40 billion in public investment, an equal amount I'm sure on the private side, and then the sweat equity of providers and health IT developers getting all these systems in place, to the point that now we have 97% of hospitals and over 90% of ambulatory offices on Certified Electronic Health Record systems, right. That's a huge accomplishment in a relatively short time, and it took a ton of work to get that in place.

Now I have the opportunity to say that's all in place. Now, how do we think about what it is we want to do? So to answer your question Mark directly, what are the things that you know already we're able to do? If you think about interoperability, for example, a lot of people don't appreciate that a lot of interoperability actually happens today. So the Care of Quality Network that now exchanges allows exchange of information across health IT, you know, different EHR vendors, while not perfect and while it doesn't cover, you know, all of the hospitals in the country, it covers something like 70% of hospitals and a large number of ambulatory positions. They do 50 million transactions per day, healthcare transactions per day. And just to give you a benchmark, the global banking network Swift, that a lot of us have heard about because of the Russia-Ukraine crisis. Swift does 41 million per day.

So just as, and Care Quality alone, doing 50 million that doesn't even include what Epic does within Epic's own network care everywhere. And what Commonwealth does within its own network. So it's a lot of that baseline interoperability that's happening today, which is great. Yes we weren't able to get a lot of data that we wanted to be able to get during the pandemic. But the information that we were able to get, for example, on COVID vaccination rates, for

example, all of those things, the immunization registries that's hell of a data, the only way they got that data was from feeds from EHR systems, right. That's how they got that data, HL7v2 feeds in the background that were pushing that data into those systems. So there's a lot of interoperability that's happening. But it's not merely good enough, right, we don't have the kind of interoperability that we want to be able to have for public health, to have payers be able to have the interoperability they want, for individuals. And I'll just give one small example, here, I am helping my mother who broke her hip about a month and a half ago -- and we're going from hospital to rehab a mile down the road from each other. They exchange patients, you know, 10 gazillion times a year, they're both on very good EHR systems. And right in front of me, they are printing records out and handing them to the ambulance driver. And then at the rehab hospital, they're scanning them in even though they're both on EHRs and they're both connected in the back. I know they are. So I'm just like you're killing me here, you're doing this right in front of me.

Margaret Flinter: As your mother is saying, what about me? What about me?

Micky Tripathi: You're right, exactly. So there's a lot more work to do. So I don't want to pretend there isn't. There's a lot more work to do in interoperability, but a lot is already happening.

Mark Masselli: Hope your mom is doing better.

Margaret Flinter: Absolutely.

Micky Tripathi: Yes.

Mark Masselli: I hope you're also handing a note to both of the CEOs of the organization, telling that story it's like oh! my God, your mom is saying, "I thought you solved this problem, son."

Margaret Flinter: Exactly.

Micky Tripathi: Like your life's work and you know we're still doing this, yeah. Well it was funny because I was talking to one of the vendors, you know, I was talking to and I just sort of explained that it was like, wait a minute, and then he called his account manager, he is like the National Coordinator is in your hospital–

Mark Masselli: Like literary it gets down to what you said, you got the technology, the processes, but the people sometimes just don't –

Micky Tripathi: Right, exactly. Yeah and the vendor is like they are connected,

I don't know why the front desk people don't realize that they are connected, you know, that's the issue, it's complicated.

Margaret Flinter: Well, there's one issue I'd really like you to comment on. Health Equity is such a compelling issue for all of us in healthcare now, and I understand your office has just made an announcement regarding Health IT Equity. So please fill us and our audience on this.

Micky Tripathi: Yeah, sure. So we, you know, we were doing a lot of work in what we think of as Health Equity by design. So, you know, basically the idea is that just in the same way that we think about privacy by design, safety by design and software development and in business process, we think that Health Equity ought to be sort of a core design consideration as well. So thinking first about the data as it relates to having social determinants of health data and other data like sexual orientation, gender identity, included in the U.S. Core Data for Interoperability, which is that basic data that needs to be exchanged, as well as adding additional data elements related to functional status, for example, disability, and cognitive status, for example, as you know, other categories of data that were really important to Health Equity, because that has to start with those pieces. And then we have some leap awards, you know, some innovation grants that, that we've just awarded that help us, you know, move further to, you know, think about different ways that we can have, you know, better use of Health Equity and Health Equity related information, and more fundamental thinking of how do we bake Health Equity into everything that we do.

So, you know, we're really excited about having that be a part of the way that people design and think about systems moving forward, as well as being able to have innovation grants to help people sort of leap forward to the best technologies to help us move ahead, which is hopefully something that everyone then will follow.

Mark Masselli: Micky, Margaret, and I want to thank you for joining us today. Thank you for the knowledge and energy, passion, and professionalism that you bring to your job. And we want to thank our audience for being here. You can learn more about Conversations on Health Care and sign up for our email updates at www.chcradio.com. Thanks again.

Micky Tripathi: Thank you, I enjoyed it.

Mark Masselli: Really appreciate it.

Micky Tripathi

[Music]

Mark Masselli: At Conversations on Health Care, we want our audience to be truly in the know when it comes to the facts about healthcare reform and policy. Lori Robertson is an award winning journalist and Managing Editor of FactCheck.org, a nonpartisan, non-profit, consumer advocate for voters that aim to reduce the level of deception in U.S. politics. Lori, what have you got for us this week?

Lori Robertson: President Joe Biden boasted of a decrease in premiums for Medicare Part B as the first reduction in more than a decade. That's true, but he neglected to mention the drop follows a large increase the prior year, partly due to anticipated Alzheimer's drug expenses, which didn't actually materialize. The seesawing premiums have seniors paying $5.20 cents less per month for 2023 than they're paying this year, but $16.40 more compared with 2021.

In a September 27 speech, Biden touted provisions in the Inflation Reduction Act that will lower prescription drug costs for some Medicare beneficiaries. The President added that there was more good news for seniors with Medicare Part B, which covers physician and outpatient services, “The Department of Health and Human Services announced that the premium for Part B will in fact decrease this year. For years that fee has gone up. Now for the first time in more than a decade, it's going to go down.”

It's technically true. Part B premiums will go down for 2023. And it's the first time that has happened since 2012. But there's more to the story. Last year, the Centers for Medicare and Medicaid Services announced that the monthly Part B premium would be going up by $21.60. CMS explained that it was partly due to COVID 19 expenses and a pandemic related limit to premium increases the prior year. It also noted uncertainty around potential Medicare spending on Alzheimer's drugs, specifically Aduhelm. These types of physician administered drugs are covered under Part B, not Part D, which covers pharmacy prescriptions.

The drug had been approved by the Food and Drug Administration in June 2021 through an accelerated approval process that was criticized by health experts. At the time the drug was supposed to cost $56,000 a year. Several months later, the drug’s manufacturer dropped the price by about half. Then in January of this year, CMS proposed that Medicare cover Aduhelm only for seniors in clinical trials, citing questions about whether the drugs benefits outweigh the

risks. CMS said that lower than expected expenses on Aduhelm and other services caused excess reserves for Part B. It announced the monthly premium for next year would be $164.90 or about five bucks less than seniors are paying this year.

And that's my fact check for this week. I'm Laurie Robertson Managing Editor of factcheck.org.

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like check, email us at www.chc.radio.com. We'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

[Music]

Margaret Flinter: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. Louisville, Kentucky has consistently been on a Top 20 list of U.S. cities you don't want to live in if you have a lung disorder. Surrounded by the nation's leading rubber manufacturing entities and nestled in the Ohio River Valley, this is a city that has grappled with pollution. Several years ago, the city's newly hired Chief of Innovation made a decision to tackle the issue.

Ted Smith: I wondered if there was something we might be able to do, new and different. Maybe the risk is concentrated in certain places and if we knew where the risk was concentrated, if that were true, maybe there would be something we could do about it.

Margaret Flinter: And through his work in public health research, Ted Smith had learned of a tech enabled smart inhaler that when synced to a person's phone, acted like a GPS for whenever that person needed to use their rescue inhalers.

Ted Smith: Essentially to put a GPS transponder on top of your inhaled medication so that when you took a puff of your medication, it would take a snapshot of what time it was and where you were. And that kind of real-time monitoring of asthma events, especially those rescue inhaler attacks, is really high value signal, and you're capturing it in real-time.

Margaret Flinter: Smith dubbed the program AIRLouisville and tracked 1100 participants over the course of a year. He said they were able to chart environmental triggers in any given area where an asthma attack occurred and chart real-time data on the

conditions and the location, giving them some great public health epidemiology data.

Ted Smith: We ended up with a very high special resolution map of the burden of asthma in Louisville, Kentucky and then that led us to explore where those little micro areas are that are problematic and what we might be able to do about it.

Margaret Flinter: More importantly, the smart inhalers gave users a feedback loop of information which allowed them to better manage their exposure to known asthma triggers.

Ted Smith: One part of the use of the technology is the surveillance. But another part of the technology is the feedback loop to the user who learns how poorly controlled or not their asthma is or how adherent they are with the medication they're supposed to be taking daily. And there is an immediate effect, people end up getting better control of their respiratory disease.

Margaret Flinter: Reliance on emergency inhalers dropped 78% among participants and the city was now armed with data that could help them devise pollution mitigation strategies.

Ted Smith: With the harder problem that I think the rest of the country has, which is our ambient air quality standards are still not low enough and people are exposed to levels of pollution that we are going to have to work hard to figure out how to remove.

Margaret Flinter: A tech enabled smart inhaler that gathers meaningful data that informs public health officials how they might reduce the burden of asthma health costs while teaching asthma sufferers to better control their disease and stay healthier. Now that's a bright idea.

[Music]

Mark Masselli: I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and health.

[Music]

Marianne O'Hare: Conversations on Health Care is recorded in the knowledge and technology center studios in Middletown, Connecticut, and is brought to you by the Community Health Center, now celebrating 50 years of providing quality care to the underserved where healthcare is a right, not a privilege, www.chc1.com and www.chcradio.com.