“Patients Own Their Health Data, Which Is More Valuable If Shared” (Deven McGraw) [#46]

March 1, 2023
Brad Power

“Overall, it's an exciting time for the patient empowerment movement. At the same time we see where the puck is going, and it's looking good, and it's taken way too long to get there.” – Deven McGraw

Meeting Summary

Getting access to and controlling one’s medical records can increase a patient's (or caregiver's) knowledge about their disease. This knowledge is power. It can enable a patient (or caregiver) to actively participate as a co-pilot with their medical team in guiding their testing and treatment decisions. Advanced cancer patients also want to share their health data with experts and peers, and they want to learn what has worked and hasn't worked for other patients with a similar profile. Patients' health data is more valuable if shared.

Deven McGraw is uniquely qualified to talk about the legal and regulatory situation for patients who want to get copies of their medical records and share them. She is Lead, Data Stewardship and Data Sharing, at Invitae, a genomic medicine company that provides clinical genetic testing and helps patients gather their full records (genetic and phenotypic) for use in seeking care and advancing research. Previously, she was a co-founder and the chief regulatory officer for Ciitizen, a consumer-health technology start-up. She directed U.S. health privacy and security as Deputy Director, Health Information Privacy, at the HHS Office for Civil Rights and Chief Privacy Officer (Acting) of the Office of the National Coordinator for Health IT. She is widely recognized for her expertise in health privacy. She directed the Health Privacy Project at the Center for Democracy & Technology for six years and led the privacy and security policy work for the HITECH Health IT Policy Committee. She also served as the chief operating officer of the National Partnership for Women and Families. She advised health industry clients on HIPAA compliance and data governance while a partner at Manatt, Phelps & Phillips, LLP. Deven graduated magna cum laude from Georgetown University Law Center and has a Masters of Public Health from Johns Hopkins University.

Patient rights for access to health information depends mainly on HIPAA (The Health Insurance Portability and Accountability Act of 1996), which has been around for decades, and the Cures Act, which was signed into law in 2016, and includes information blocking rules. There has been progress in making health information more accessible to patients through technology, but more needs to be done.

What are the barriers to accessing and sharing healthcare data that patients and caregivers face? What are your legal rights?

The health system facilitates gathering data for drug discovery by researchers, but accessing and sharing clinical data with physicians or peers for clinical decision-making isn't as easy. The information blocking rules and HIPAA give you a right to any data that has been created that is used for clinical guidance or to seek payment for care. Beyond information stored in medical

records, you also have a right to access the underlying raw data files and to images. You cannot use the law as a way to force diagnostic companies or providers to generate data that they haven't already generated.

What should patients (and caregivers) do to access and manage their healthcare data?

We're moving beyond HIPAA to improve patient access to their health data, including the ability to get that data through a completely online experience, such as through an app. HIPAA access is being more robustly enforced. New information blocking rules prioritize access by patients or apps acting on their behalf. Patients can get access through portals, apps/APIs, and other mechanisms.

Do the rules give patients control of their tissue and other sources of their health data?

The access rules apply only to data, and not to specimens. A biospecimen is not going to be accessible by you.

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Meeting Notes

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SUMMARY KEYWORDS

patients, data, access, hipaa, generated, files, test, image, rules, blocking, entity, question, research, information, clinical, clinician, request, lab, purpose, year

SPEAKERS

Deven McGraw (39:10), Brad Power (6:42), Rick Stanton (5:06), Richard Anders (3:58), Brian McCloskey (2:40)

Outline

Brad Power 0:03

We're honored to have Deven McGraw today with us. She's going to be talking about stuff around data.

I've known Deven for a while from her pioneering work when she was a Ciitizen. She's a lawyer by training, so she's an expert on health data. Advanced cancer patients are interested in using their data to help them make clinical decisions. The aspect that we're interested in is: what should we be thinking about in terms of accessing and sharing our data so we can get better insights?

Deven McGraw 2:01

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I am the lead for data stewardship and data sharing for the Ciitizen platform. I need to update that because when Ciitizen got acquired by Invitae, I got a bigger job. Invitae is a clinical genetic testing company. Ciitizen is a platform that helps patients to leverage their rights under federal law, at least here in the US, to get access to all of their health information, so that they have it at their fingertips and can use it as they wish and share it as they wish, whether it's for involving a caregiver, or seeking treatment options, or contributing data to research, or all of those things.

I was formerly with the HHS Office for Civil Rights, which is all things HIPAA (The Health Insurance Portability and Accountability Act of 1996 is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.), so policy and enforcement of the HIPAA Privacy and Security and breach notification laws, and also did a stint as the Acting Chief Privacy Officer at the Office of the National Coordinator for Health IT, which sets the standards for electronic medical records and more recently, policies around some new laws, called the information blocking, or Cures Act regulations.

> *Most clinical information is digitized, accessible, and shareable thanks to several technology and policy advances making interoperable, electronic health record systems widely available. In 2016, the 21st Century Cures Act (Cures Act) made sharing electronic health information the expected norm in health care by authorizing the Secretary of Health and Human Services (HHS) to identify "reasonable and necessary activities that do not constitute information blocking." ONC's 2020 Cures Act Final Rule established information blocking exceptions to implement the law.*

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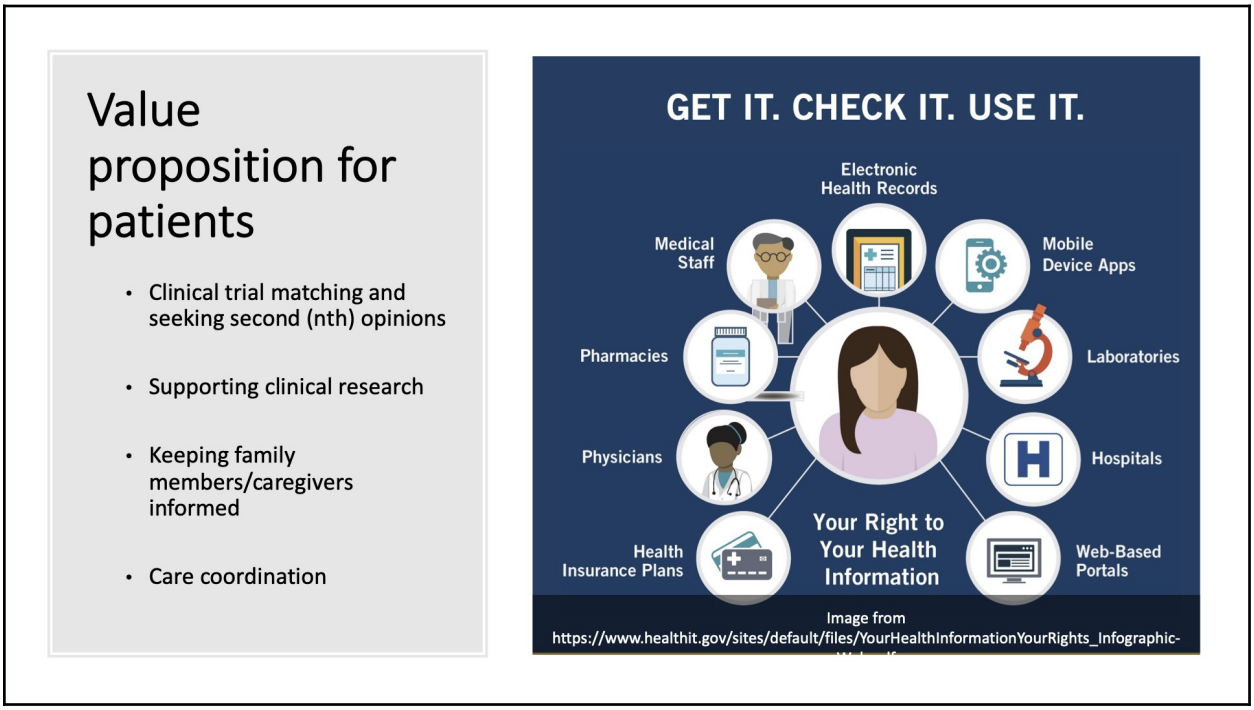
I have the same caveat that Brad started with, which is that I'm going to give you a presentation about the laws and policies that facilitate patient access to their data, but I'm not your lawyer, and I cannot give you legal advice. That's really about the application of law to a particular set of factual circumstances so that you understand how you might be in compliance. This will help you understand the parameters of the law, but I can't be your lawyer or somebody will get me into trouble, as much as I would like to.



I always start with a bit of a value proposition for patients. I feel like for this crowd, I don't really need to do that. You all are pretty well convinced. The ability of patients to seek treatment options for themselves, including clinical trials, depends on your data. You can't know if you match to a clinical trial without your data. Being able to support clinical research, keeping others informed of what's going on with your care so that they can be helpers to you. And then of course care coordination. This is an infographic that comes right from the Office of the National Coordinator for Health IT.

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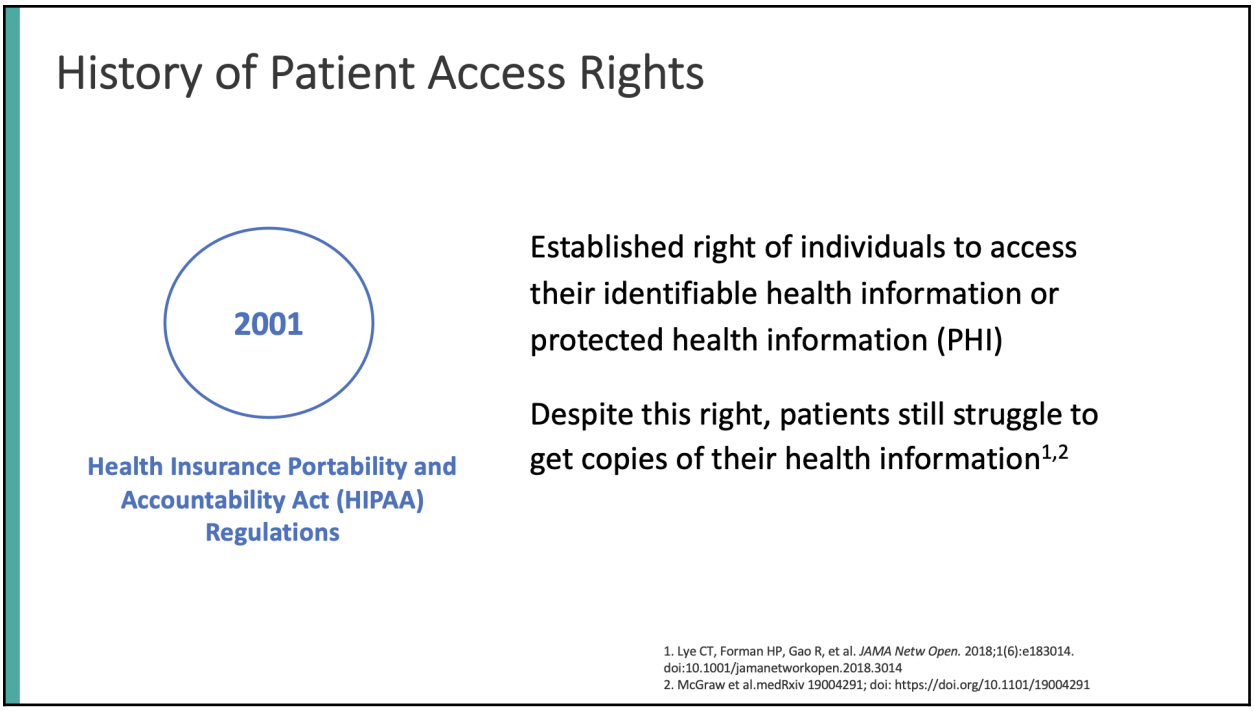

We've been talking a lot lately about the rights of patients to get their data, and the tone of some of the discussion makes you think, “Oh, this is a new thing; the Cures Act established new rights,” and the reality is that it actually didn't. They're the HIPAA privacy laws which were finalized and put into effect for most entities covered by the law in 2001 – well over two decades ago. It established the right of individuals to get access to and a copy of their identifiable health information, which is otherwise known as protected health information or PHI, under the law. Now, despite this, right, we know from literature, and probably a lot of you from personal experience, that this is not easy to exercise. There are a lot of obstacles often to getting these records sometimes. I have heard stories of organizations outright telling people, “HIPAA won't let you get a copy of your data.” When, in fact, the opposite is true. But even if someone is granting you this right, sometimes the barriers to getting that right can be pretty significant.

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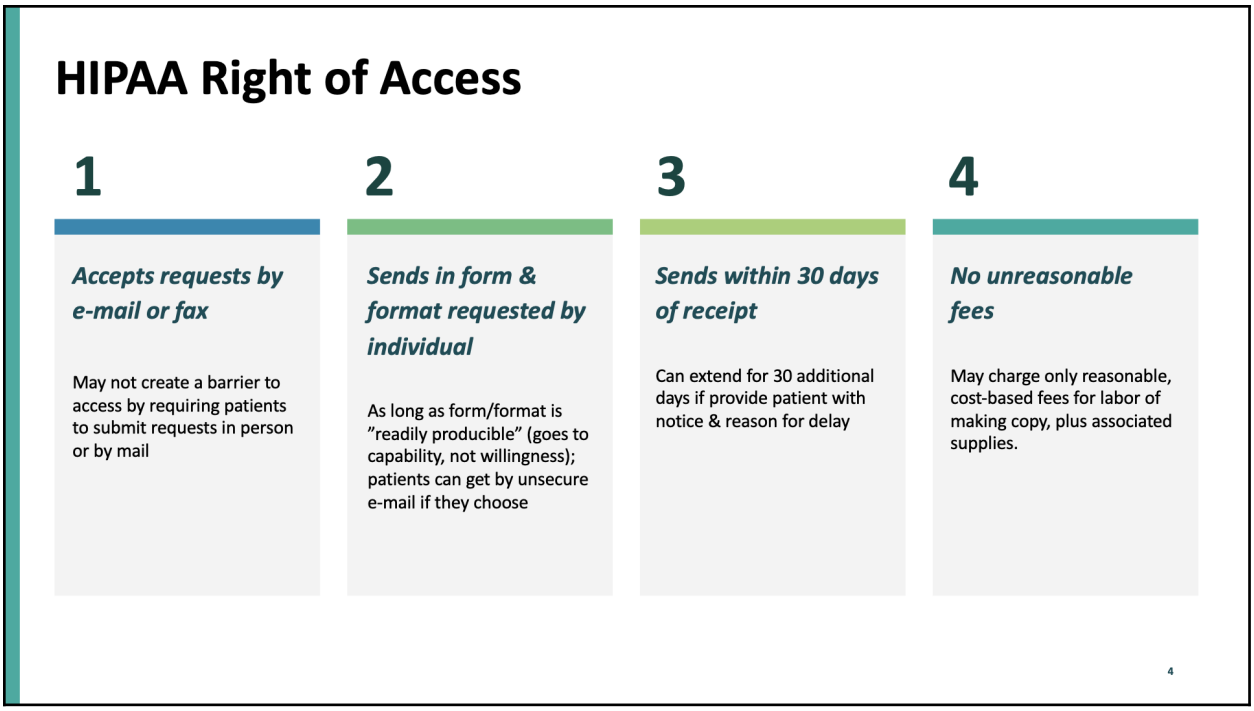

The scope of the right is actually really broad. I helped to write some guidance when I was at the Office for Civil Rights, to try to clarify that this right has a lot of parameters to it that are favorable to the patient. You can't make a patient come in person to get their data. They have to have some way of getting it remotely. You need to provide it to the patient in the form or format that they request, as long as you're technically capable of providing that to them. HIPAA provides that they can take up to 30 days, and can extend for an additional 30 days if they have to go offsite, for example, to get your information. In a minute, we'll talk about how the information blocking rules improve on those timeframes. HIPAA does allow for fees to be charged, but they're supposed to be reasonable and cost-based. And not necessarily per page, if what you're getting is digital copies of a digital document. This is another area where we see a lot of friction where patients are given bills for sometimes hundreds or thousands of dollars for access to their health information. More than likely those fees, unless they really are really old paper records for which a per page fee can be charged, are higher than they should be when they're imposed. Sometimes organizations give them for free to patients. But I do see charges from time to time.

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We're moving beyond HIPAA somewhat rapidly to greater facilitation with data, including the ability to get that data through a completely online experience, such as through an app. I don't think we're moving quickly enough. But we definitely have made a lot of progress in the last two to five years on accessibility of a core set of health information for patients. It's not nearly in the volume that's as impactful for cancer patients in particular, because the volume of data that's produced about them and in a clinical visit is pretty voluminous, and oftentimes not always available through an online kind of portal. But that situation should improve over the coming years because of some other other federal initiatives that I'm going to talk about next.

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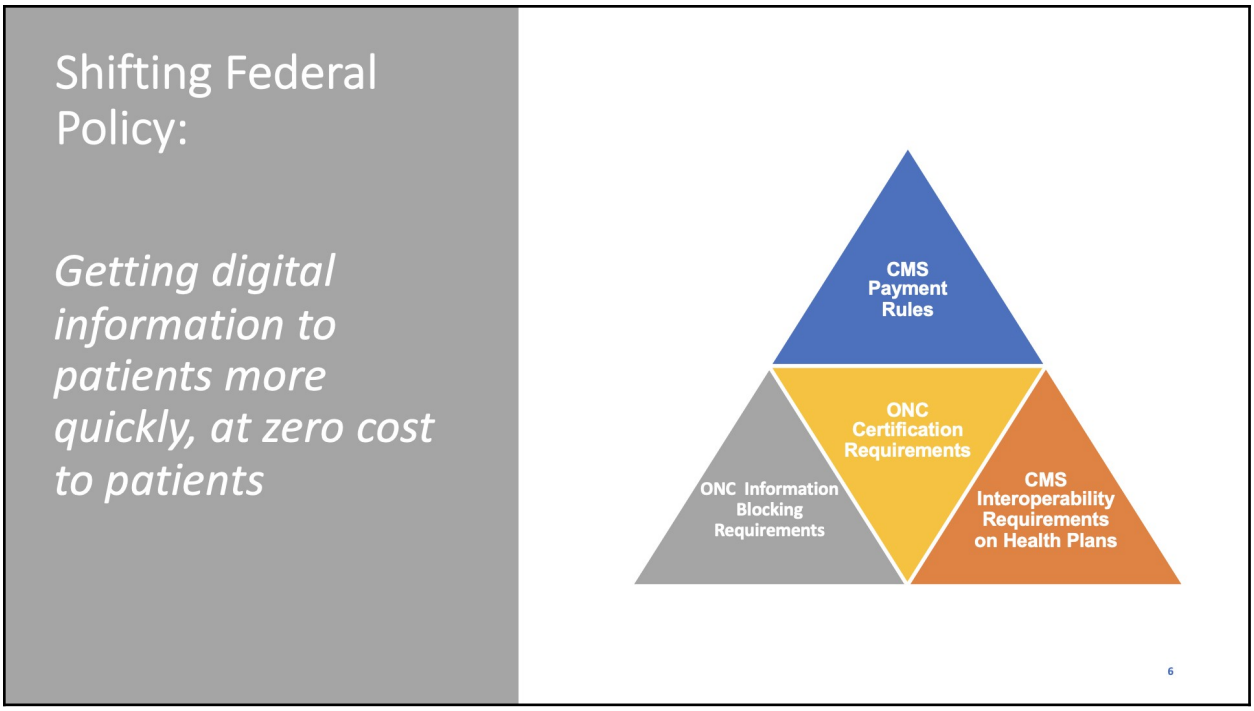

HIPAA is no longer the only set of federal policies that lean very heavily towards favoring patient access. There are now payment incentives under Medicare and Medicaid for clinicians to make data accessible to patients. There are certification requirements in the electronic health record tools that many clinicians utilize that provide capabilities to make data more available to patients such as through application programming interfaces that are open and standard in accordance with “fire”, FHIR – the fast healthcare interoperability resource. Those capabilities have for the past couple of years been more widely adopted in the customer base for these EMR vendors.

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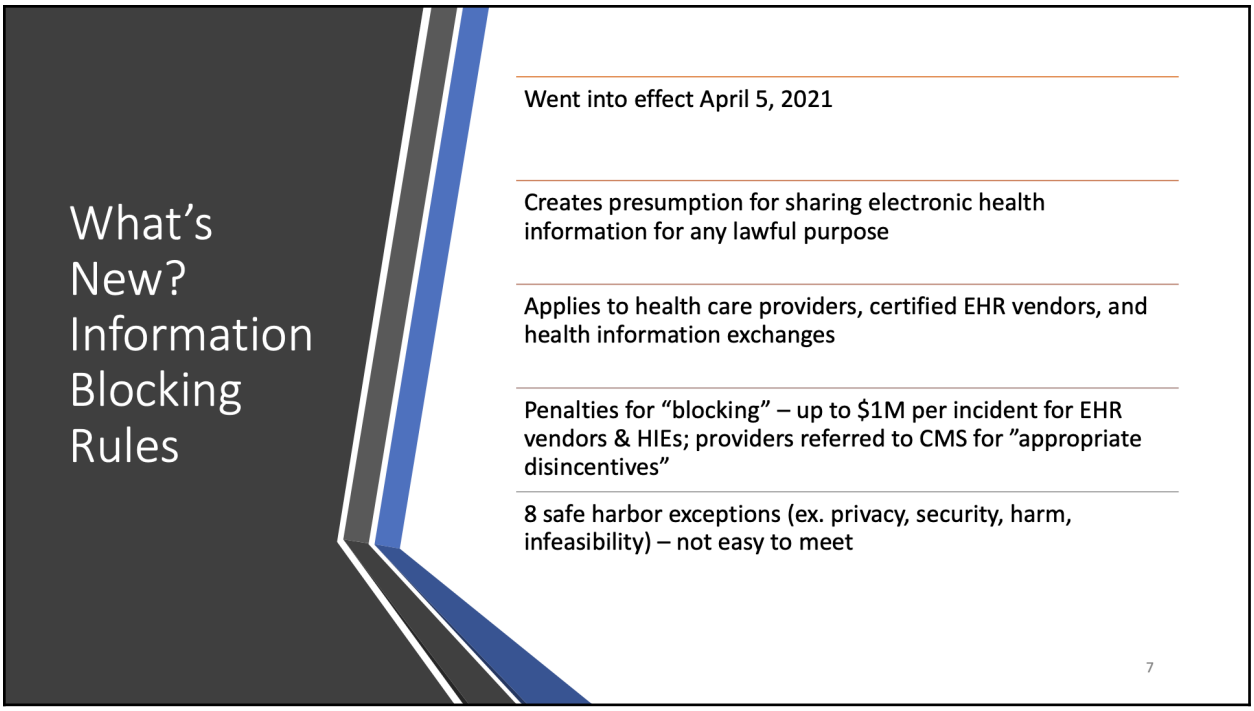

There are also new information blocking requirements that came out of the Cures Act. The information blocking rules, otherwise known as the Cures Act rules, play a really important role or will play an important role. They are nascent. What are these information blocking rules? What do they say? They went into effect on April 5, 2021. They're not being enforced yet. But we know that the Office of the National Coordinator has received a lot of complaints, particularly about healthcare providers not complying with the information blocking rules for patient access. They create this presumption that an entity covered by the rules must share electronic health information. Providing access to patients is not just a lawful purpose, it is a required purpose under HIPAA. So there's an emphasis in the information blocking rules on making sure that patients can access their data even though these rules don't just apply to patient access. It applies to healthcare providers and certified electronic health record vendors like Epic and Cerner, and these entities called health information exchanges (HIE), which exist across the country in states and sometimes with bordering state regional exchanges. They have typically exchanged information among medical providers for treatment purposes, but they are beginning to open up for other purposes. Because the information blocking rules put pressure on them to do so there are penalties associated with blocking. You can be fined up to a million dollars if you are an electronic record vendor or an HIE, and you've been found to be information blocking. Medical providers are going to be referred to CMS for appropriate disincentives. We don't know what those look like yet. We're anticipating a proposed rule to come out of the Office of the National Coordinator to propose those disincentives. It'll probably be at least another year before those get finalized. There are some Safe Harbor exceptions that an entity covered by these information blocking rules can rely on if they declined to share data, or otherwise make sharing data more difficult.

Deven McGraw 11:58

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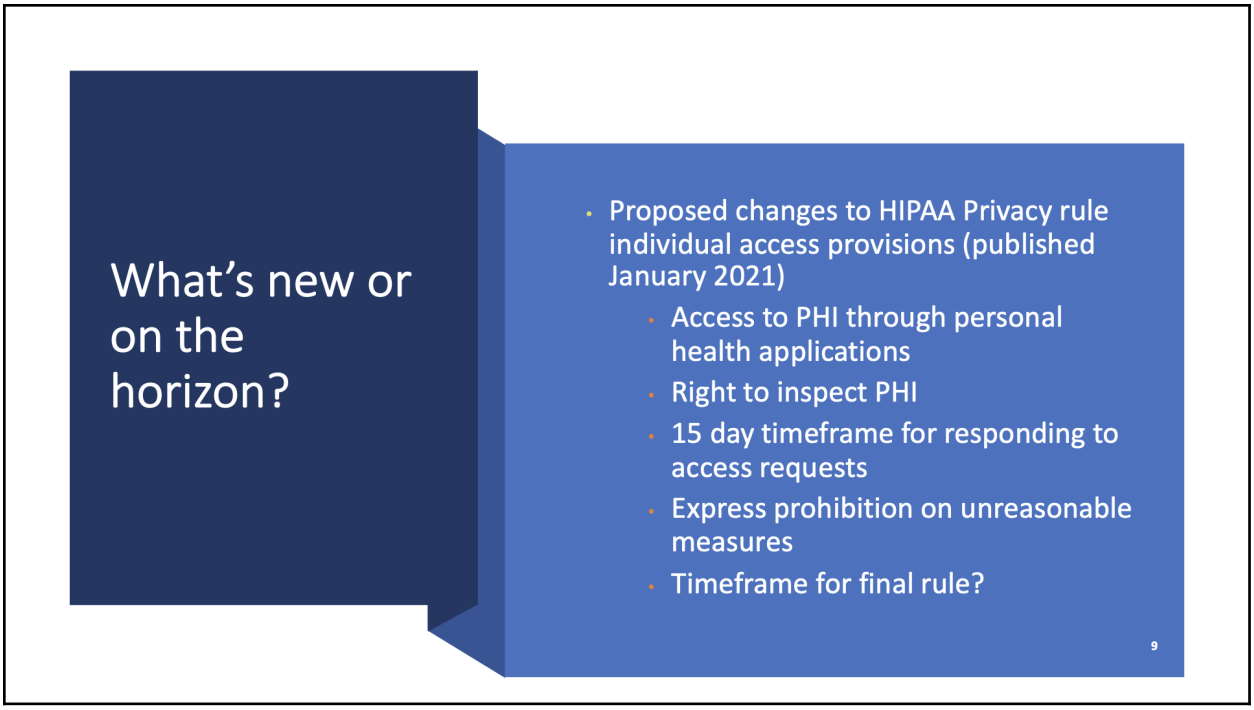
They're not easy to meet, though. It's not like a healthcare provider, for example, can say, “Oh, I decided not to share with the patient for privacy reasons.” They can't just generally say that they have to really document with some specificity why they declined to provide access to a patient. And because HIPAA already requires these entities to provide data to patients, it would be a hard case to make, unless for example, they had some sort of policy that they had newly implemented requiring additional patient consent. Now, again, these patients are getting their own records, so that policy would have to be judged about whether it placed additional burdens on patients. But suffice it to say that there are some exceptions that were designed to protect legitimate behaviors around data sharing that are important to preserve. But they have standards that have to be met before they apply. It's not like an entity can just decide, “Oh, I'm withholding this data or placing additional obstacles to sharing it because of privacy. And I decide the parameters of what that means.” If you're going to make a judgment call, and not make information easy to share with the patient, you better have a darn good reason and document that.

Deven McGraw 13:29

We have an environment now where patients are increasingly getting greater power in terms of accessing their data.I referenced the HIPAA right of access earlier. For a long time, notwithstanding the guidance that made it more clear just how broad this right is, and greater expectations on entities for complying with it, it wasn't really enforced very robustly. But over the last three to four years it has been, and that has improved data sharing immensely. It doesn't mean there aren't pockets of areas where they're still non-compliance, but it's in better shape than it was five or six years ago. The information blocking rules prioritize access by patients, or

applications acting on their behalf like a Ciitizen app or Apple's health app, to just provide two examples. The information blocking rules set an expectation that it wouldn't take 30 days to produce a digital copy. For patients there are not specific timeframes necessarily other than some guidance out of the Office of the National Coordinator, basically saying that with respect to patient portals, if the lab result is available to the clinic to the ordering clinician, then it needs to be available to the patient, if the patient wants to see those results without any delay. You all may be aware of a lot of discussion about this, because there are some members of the medical community, the professional societies in particular, that are opposed to this, they want a delay. They're not asking for 30 days, they're typically asking for 48 to 72 hours. As a consequence of this dispute, and the federal agencies standing firm with the patient's right to get that data right away, we're seeing some state activity to require labs and medical professionals in that state to impose a delay before getting results to patients. We can talk more about that if you'd like. Again, because the certified electronic medical records now have to have this functionality that can enable patients to plug in and get their data more easily, there's a lot of federal policy that's aiming at that pathway as the pathway for getting data, but it's really up to the patient. The patient does not have to use a portal to get their data if they don't want to. They also can prefer to use the portal as the mechanism to get their data, as long as the data is of the type that can be accessible through that portal, which is not all data at this point. Image files, for example, are typically not available through that mechanism. Yet some providers have done the work to do that, but not all.



What's coming up to get excited about? Not every entity covered by HIPAA is also covered by information blocking rules. Health plans, for example, are not subject to the information blocking rules. They're still subject to HIPAA and CMS rules if they're regulated by CMS. There are some proposed changes to the HIPAA privacy rule that would raise the bar on the baseline that

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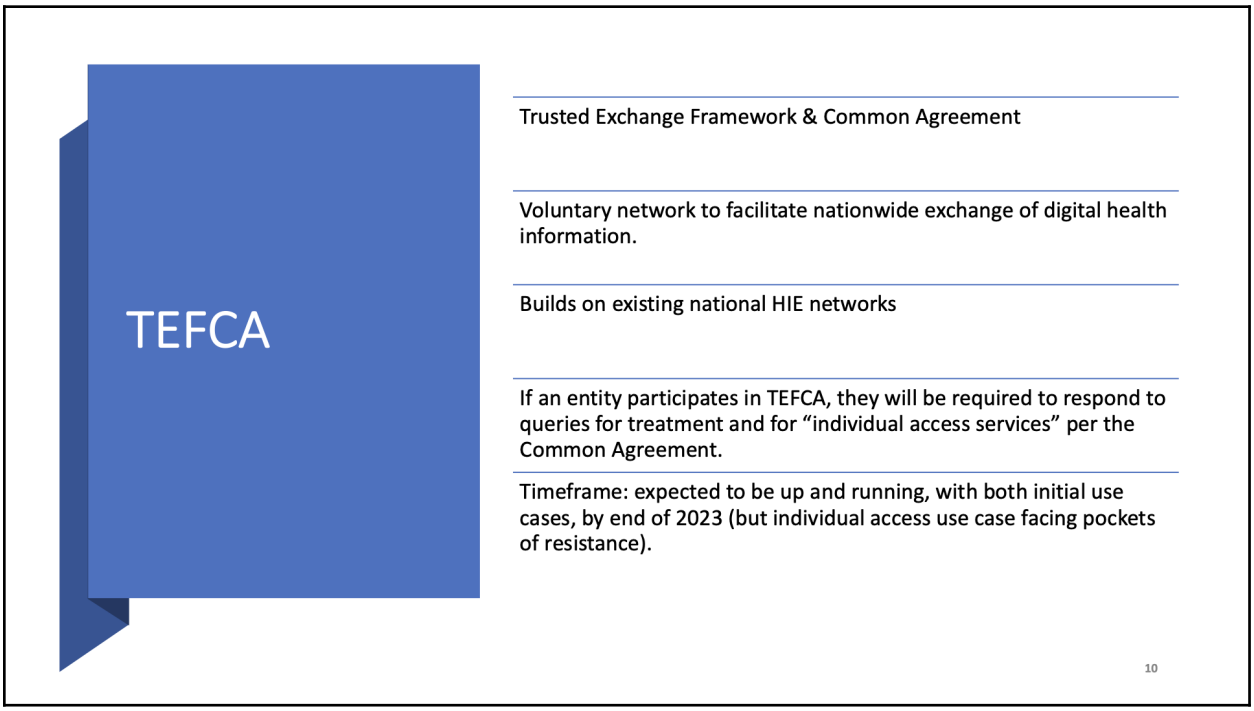
HIPAA establishes for right of access, including expressly prohibiting certain unreasonable measures and a 15-day timeframe for responding to access requests. We're not sure when those are going to get finalized; I expect this year. Early this year would be when they've projected it, but they almost never meet their deadlines. So it's kind of hard to say.



There's also this thing called the TEFCA, which is the Trusted Exchange Framework and Common Agreement. This is a voluntary network designed to facilitate the nationwide exchange of digital health information. It builds on these health information exchanges that I was talking about earlier that exist throughout the country, and largely just facilitate exchange for treatment. A number of the others picked up public health use cases during the pandemic, some of them also exchanged with payers. But the idea is to assure that they can connect to one another nationwide for a broader range of purposes, including the ability of patients to essentially have a query launched through this network and get data in return. So rather than having to go to each portal of their doctor, if their doctors participate in this TEFCA, or the doctor’ medical record networks participate in TEFCA, the idea is a single on ramp and data from all of those sites being able to be delivered.

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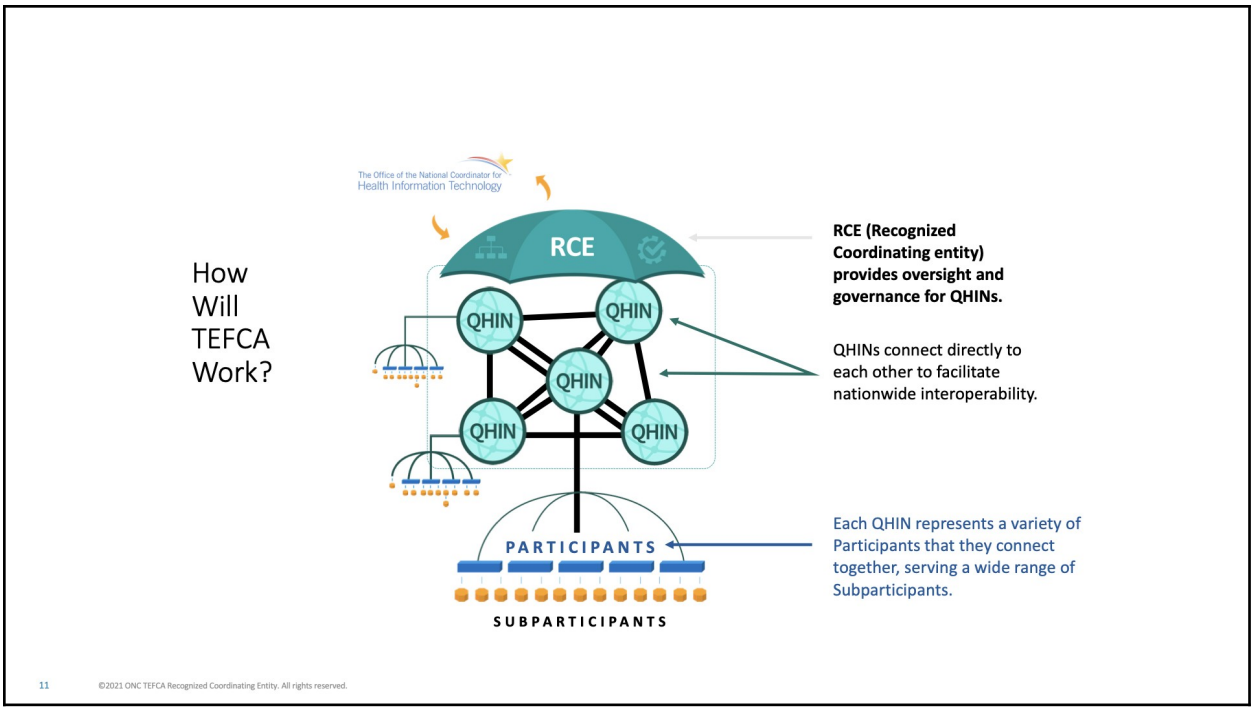

Here's a diagram of what this is supposed to look like. There's a coordinating entity at the top, that's the Sequoia project. And then there are these anchors for this nationwide network that are called QHINs, or Qualified Health Information Networks. And then participants are expected to have a way to launch a query through one of these QHINs, and then the QHINs all connect to one another and can facilitate the exchange of data.

Overall, it's an exciting time for the patient empowerment movement. At the same time we see where the puck is going, and it's looking good, and it's taken way too long to get there. And so the fact that we don't have everything that is on the horizon as tools that we can use today is a bit frustrating, and there are still some entities pushing back hard on this and trying to make this hard for patients to exercise. We can talk about some of the obstacles that we're seeing as well.

Brad Power 20:11

The patients in our community are very aggressive about getting diagnostic information. They've already moved beyond getting access to their medical records. That's assumed. What's interesting is, if I go to Foundation Medicine, or to Tempus, and I get whole genome raw sequencing files, it's a very big file. It's never going to sit in the medical record because a medical record system can't handle anything that big. So I don't get it there. I have to go to Tempus or Foundation Medicine to get access to that. Do these HIPAA rules and the patient access apply in this sphere for these kinds of data?

Deven McGraw 21:04

They do. In fact, we were very clear when I was at the Office for Civil Rights, that, first of all, clinical laboratories are subject to the HIPAA right of access. As long as they are laboratories that bill for the delivery of laboratory services to some degree, they are covered. For example, Invitae, for whom I work, is covered, as is Myriad, or Color. The only labs that might not be covered by this would be if they're solely direct-to-consumer. But I think most of the labs that would have this type of clinical raw data files that you're looking for, would be covered by the HIPAA rules and covered as medical providers under the information blocking rules. We also made clear in guidance, that the right of the patient to get data extended beyond the laboratory, beyond just the test report itself, but to the underlying files that created the data, that the patient has the right to all information in what's called “a designated record set”, which is not just information in the technical medical record, however that gets defined by a particular institution, but any other information that might exist that the entity generates or collects that is of the type used to make decisions about patients. The idea is that the underlying raw data files are utilized to generate the report, which is a decision about a patient, and so you have the right to that underlying data. Now, of course, it's probably never going to be available in a portal because the files are so large, and there's a negotiation that happens around the format in which these files can be delivered to you because they are so large, but that's supposed to be a negotiation with you, so that you're getting it in a way that works for you, and that can be produced by the entity. There is a specific FAQ on OCR 's website on this topic. I'm be happy to provide you with the direct link to that, because I was there when we drafted it.

Brad Power 23:17

That's very cool, because we sometimes go hat in hand, begging for that information. There are a couple of related issues. Sometimes a diagnostic company will collect data that they don’t tell patients they are collecting.

Rick was very interested in getting access to novel tests like spatial analysis, which was “Research Use Only” tests, that are typically not given to patients because they're not meant for clinical guidance. That's what Research Use Only means. But Rick was able, through the help of Nik Schork, to get an IRB that would allow him to see his data.

Deven McGraw 24:33

I would love to hear about Rick's experience. That is one where you'll have to go hat in hand because it's not clear to me that you can use the law as a crowbar, because it's not designated record set information if it's research use only.

Rick Stanton 24:51

The spatial companies were so promising. But then they really dug in their heels when it came to Research Use Only. They wouldn't even run the data, let alone provide access. And because there was no data, they wouldn't work on my tissue. That was very disappointing. We were all hoping for immune oncology insights that might open those immune oncology doors that are

pretty shut for us prostate cancer patients in general. That was a big frustration. I was just at the end, just trying to open the door, even if it was old tissue, just give me a report. Let me see what you could do. But that didn't happen.

Tempus produces RNA seq data on everyone they do genomics sequencing on, but it's typically not even mentioned, or it may be mentioned, but it's not provided to patients typically. It seems like that is an opportunity to get more clarity and help because the average patient that goes into the doctor's office, or a Comprehensive Cancer Center, and they get sequencing, it might be a number of shops, and one of them might be Tempus, or it might be another one. I don't know the standard procedures of other companies, but Tempus runs RNA seq on everyone, and just doesn't provide that data. It’s just part of their collection. Someday, that'll be a treasure trove, hopefully, of statistical value. But patients don't get that typically. It's not a large file. So it can be percolated down into RNA reads, reads per million transcripts for a million, which is about 80 kilobytes of data for 20,000 rows, a few columns. I would like to see that be more transparent, and everyone get their data, rather than some kind of hand wave or it's too big, or it's not actionable.

That's another thing. What was actionable yesterday does not define actionable today, as we're pushing forward. My oncologist wants to know, “What are we going to do with that data? Why do you care?” And my response would be, I'm looking for therapeutic opportunities, not just from genomics, but from gene expression. But is it actionable? Do they have to release it? Because it’s not really actionable, according to many people. I invite you to add any response to that situation that you wish.

Deven McGraw 28:37

The size of the file is mostly only relevant to how it ends up getting produced for you. The most relevant question is whether that RNA seq data that Tempus is supposedly generating, I'm saying, “supposedly”, because I don't have any insight or knowledge of Tempus practices. But if they're generating it on each and every test, or some segment of tests, if you can get get some evidence of why they do this, and what they use that data for, and then figure out if an argument can be made that it's “designated record set” data, like if they're generating it for something that has nothing to do with test interpretation, then it's going to be harder to argue that it's designated records or data. Even though it was generated off of your test, it still has to meet that definition in order to be subject to both the Cures Act rules and the HIPAA rules regarding whether you could use the law as a crowbar to access it as opposed to making a passion plea to these entities. The other thing I'll note is that nobody has to produce data for you that they're not already producing. The information blocking rules and HIPAA give you a retrospective right to what they've created that meets the designated record set definition.

It applies only to data, and not to specimens. You alluded earlier to a desire to have them run some tests on specimens that they preserved from you. It is unfortunate that these rules apply only to data. That biospecimen is not going to be accessible by you, nor can you use the law as a way to force them to generate data that they haven't already generated. If they've generated

the data, then it gets to, “Why did you generate that data?” And, “Can I make a plausible argument that it's subject to these rules?” If that makes any sense? It's not perfect In terms of getting everything that you would want.

Brian McCloskey 31:06

These companies are selling their data to big pharma for drug development. So how does HIPAA or the law come into play in terms of protecting the rights of patients? Because essentially, you have a company who's profiting from patient data.

Deven McGraw 31:38

The only way they can profit from patient data without your consent is if they've de-identified it in accordance with HIPAA standards. We could have a long conversation about how that fits in once they de-identified it. Then there are “sale of data requirements” in HIPAA that would require you to authorize that, but they'd have to be selling your identifiable information versus information that met HIPAA’s de-identification standards, which does not require anonymity, it just requires reduction of risk to very low risk of re-identification. So that's that piece. But even if they're selling HIPAA de-identified data, if you are seeking data that meets designated record set definition, it's yours, regardless of whether that might impinge on their market opportunities to sell the data, license the data, however they do that, you can still get your copy. And their proprietary interest in that data is secondary to your ability to access it. But only the categories of data that meet the “designated record set” definition. So all of this other data that might be being generated, for example, research data only, that is never used for clinical decision-making or laboratory result generation, is going to be harder for you to get, even though it might be subject to being monetized by the company. But again, keep in mind, the fact that there is a commercial data enterprise operated by this company does not mean that your right of access takes a backseat. That is not a reason to deny you the ability to access that information. How much evidence can you generate that some of this data that you've been seeking, that you've been denied, is in fact used by the company to make clinical decisions? How creative can you be at fashioning an argument that, “Yeah, the company might be using it for a bunch of other stuff, but they also use it to improve their clinical reads of the test?”

Brian McCloskey 34:00

We have very close ties to Tempus. They're incredibly supportive of what we do. They have a whole AWS infrastructure that patients can access directly, where all of the raw fast queue files are available, so that we can then take them in. In certain cases, we work with their bioinformaticians to figure out custom analysis for us. They're very good about that. I wanted to say that I didn't disparage Tempus because they've been truly amazing for me.

Deven McGraw 34:45

I'm glad to hear that. I think they were good to Ciitizen too, before we got acquired by Invitae. We have a patient records scorecard, where we have documented how easy it is to access data from more than 6000 providers, including labs, and my recollection, because I helped to stand up that unit in the early days, Tempus was great. Inviate was great. Some others were not so great.

Brian McCloskey 35:11

Let me push this story back a little bit. A lot of this data is generated from tissue, or blood samples, or whatever. Let's just take tissue because that's easy. Tissue goes into a biobank in my healthcare institution. The odd thing is that I don't have full control over that biobank. I don't know how much money I have – the tissue is like digital currency – in the biobank. I have some guesses. I want to be able to maximize the utility of it. I can request certain tests, of course, but sometimes that's a real hassle. I've got to convince my doctor to do proteomics, for example. Finally, she's on board. But where does HIPAA come into play relative to a patient's rights to their tissue?

Deven McGraw 36:35

Zero. When I first joined the Office for Civil Rights, I remember the senior policy advisor who had been with the organization almost since HIPAA was first drafted – She'd been there for a very long time; she had very deep knowledge – said, “We don't do parts. We just do data.” So if there's data written about your specimen, and it fits into this designated record set definition, data that you use to make decisions about patients, then it's subject to the right of access, but the tissue itself is not data. And so therefore, it is not covered by those rules. I have been in many meetings where people have said, “We need a patient movement. We need Congress to do something very similar, to establish a patient's right to access biospecimens.” But I've never seen any real movement on it.

Brian McCloskey 37:39

That's unfortunate.

Brad Power 37:43

We spend a lot of time figuring out what's the source for the data. If you don't have the tissue, you don't have data.

Deven McGraw 37:52

It makes you want to bring in an extra little container at the time when they extract, and say, “Please give me my little piece for me.”

Richard Anders 38:05

Just riffing on that, if one could persuade a clinician to do a test, once they've done the test, could you conclude they've opened the “designated record set” door, and now a patient would have access to the data?

Deven McGraw 38:22

It might be a little bit tricky. First of all, if you've persuaded that clinician to do the test, I can't imagine why they would do the test and not give you the results of it, because why else would they have done the test? But if you do face this situation, where somebody does a test at your request, but then maybe their legal department steps in and says, “We shouldn't give this to that patient. It was not generated to make clinical decisions about that patient, it was generated because the patient asked for it.” And yet, it doesn't meet the definition of a designated record set because it's information that they generate, that they use to make decisions about you. I could see a circumstance where they may tell you, “No, we're not going to do it.” Even though they never would have performed the test in the first place but for your request. It would be weird. But if they're not generating it as a clinical function for them to make decisions about you, then it becomes harder for you to argue that you have a legal right to it because it doesn't necessarily fit into the designated record set definition. If they bill for that test, it's probably what we call in legal speak, “prima facie evidence,” that they wanted to use it for clinical decision making, because they billed for it. It's an incomplete answer. It seems very odd to me that any clinical setting would run a test at your request and then suddenly deny you the results of that. But if they didn't have a clinical reason for generating the test, and they have no intent or desire or don't actually, in practice, ever use that to make a clinical decision about you, you might run into some obstacles in arguing that its designated record set definition. But the real key to using those laws that I've talked about as the crowbar to get data out, and in your hands, and data only, unfortunately, not specimens, is it in the medical record? Or is it somewhere else on the premises of that facility, or with a contractor, and it's the data that's of the type that they use to make medical decisions.

Richard Anders 40:59

Obviously, it's a bit of an unsettled area, and I guess there are penalties for failure to comply. The penalties for failure to comply with something like, say, copyright is, in theory, extraordinarily high. But in practice, no one ever pays the per occurrence $50,000, or whatever.. Presumably, a laboratory or diagnostic organization wants to work with the clinician, and these penalties are probably not a whopping crowbar, but they might be a big screwdriver. I imagine there are at least two situations where the patient is trying to pry records loose. One is a test that perhaps gets done at the hospital lab. And the other when the patient has persuaded their clinician, and the clinician has gone along and ordered the test but then the lab does not want to provide the information to the patient, as if the request has sort of vanished into the ether. The clinician made the request, presumably, because somehow they were convinced that it's for the benefit of decision-making. And once the clinician contacts the lab, perhaps they just need to say the magic words “I'm trying to make a clinical decision, could you do this test for me?” and

then, whether it's a hospital lab or an off-premises lab, maybe the patient has a pretty good lever to argue that they should get the data. Would you agree with that?

Deven McGraw 42:31

Probably in most cases, it’s a presumption that if it was a test ordered from a clinical laboratory, for a patient, it is clinical data. And absent a “research only" type of relationship between the provider in the lab or the provider saying to the lab, “This was generated in a research context only, and the patients aren't supposed to have access to it.”

Sometimes the data are generated in a mixed purpose type of environment. It's used for research, but it's also being used in your clinical care. What HIPAA says about that, and the applicable information blocking rules too, is that you might not be able to get a copy of the result that's being actively used in research if it would bias the research for you to see those results, like if you're in a blinded type of protocol or something. It's not an infinite bar to your access to those results. It's access for the dependencies of the research, and then you're supposed to be able to get it. And it only applies if it's required to not bias the research.

Richard Anders 44:03

I guess the big issue is whether getting the data would unblind the results? You certainly don't get PK data (pharmacokinetics – a technical term for a process often used in drug development to analyze how the body uses and eliminates a drug introduced into a person). because that would tell you, “There's a drug in that person.” (As opposed to them being a “control” subject who does not get the drug, but as is generally the case, does not know that they haven’t gotten the drug.) But you might get genomic expression data because often that might not be obvious evidence of the new drug, but could possibly be due to many other factors, including the natural course of the disease or the standard of care drug. So you might have a good argument to get a lot of the clinical trial record data, as well. It’s something a lawyer could have a field day with, but you certainly don’t want to mess up this relationship by bringing the lawyers in.

A lot of institutions don't have image data, but if they do, can you get an image file?

Deven McGraw 44:50

Yeah, absolutely. Ciitizen has been collecting image files for its cancer patients since our inception. We usually have to go to the radiology department to get it. On occasion, especially when we were early days, I would sometimes have to get on the phone with privacy and compliance officers and say, “The image files are definitely part of the designated record set, because you don't generate them, except in a clinical context,” again, absent a purely research protocol reason. It's a common myth among facilities or the business vendors that they often use to process information requests that, “Oh, images are not included.” Oh, yes, they are. And in fact, the guidance says so quite specifically. We've also done this for EEG tracings. We have patients on our on the Ciitizen platform with rare neurological disorders. We were getting EEG

reports. There was a value proposition to getting those underlying tracings that were generated. And we got them.

Richard Anders 45:58

I assume they'll scan them or something?

Deven McGraw 46:01

It took a bit of discussion. We usually have to work directly with a small cadre of vendors who serve that space, but they do it.

Richard Anders 46:09

Do you have access to the clinical trial data at the conclusion of the trial?

Deven McGraw

You should.

Brad Power 46:20

Switching from access to sharing a bit. I've always loved the value proposition of patients like me, that I could go look and see other patients who fit my profile and 10 tried this drug, and it worked, and 10 tried something else, and it didn't work, whatever that might be. There are only one or two observational registries where a patient could donate their data, and also then get access to other patients’ data for clinical use, for clinical guidance, and not for research. There's “Count Me In,” and there's “All of Us”, and lots of registries where you can donate your data as a patient for research, but typically patients get no feedback, you get no value, no benefit from donating your data. It's because it's being used for research purposes. What are you seeing and what is going on in the frontier? Who would be of interest to us, where I could put my data into a pool, but then see other patients' data and use it for insights to guide my testing and treatment?

Deven McGraw 47:27

I have not seen that model yet. We're not the only ones who do this, but we operate a model that allows for patients to contribute their Ciitizen data, which they also have their own copy of, to a disease-based registry that is designed to facilitate research, usually in conjunction with a particular advocacy group. We give patients the ability to share data with the advocacy group, whether it's just contact information or detailed clinical information. The step we haven't taken yet, but that is very intriguing, and that we'd love to pursue, is the idea that patients could essentially opt into a social type of sharing of all of their data and all of their accounts. At a minimum, you could all join the same personal health record platform, get all your data, and then provision access by each person in your group, to enable you to see that data or organize

yourself in a way that you've got a registry that's being contributed to, and part of the terms of the registry are that any patient who actively contributes to the registry can also see the registry for their own clinical use, or maybe they're doing community scientists type of research on that data. There may be models out there that I just haven't come across yet. I've seen a lot where patients, because it's coming out of these personal health record platforms, you get all your data, and it gets contributed to research, but you still have access to it. But I haven't quite yet seen the sort of next level dive of, “Oh, and you can join this community and not just share, like in a kind of a social group setting where you're talking about your symptoms, but allow somebody else to dive deeply into your clinical data.”

Brad Power 49:36

To put a pin on that for future reference, that is what we are doing now in our community. Brian just did a report out of that a week ago. We have a Google Drive file where everybody donates their data, and all the patients can see each others’ data, and then Brian did some aggregated analysis on that data to say, “Here are the patterns around biomarkers that seem to be prevalent,” and other things, and added some interesting data to it. We're very interested in that, as you can imagine patients would be. If you ever run into that in the future, we'd be interested in collaborating. The one that I've heard of that's all along those lines is xCures, which is affiliated with Cancer Commons, and has an XCELSIOR observational registry that's tracking people longitudinally..

Deven McGraw 50:35

The closest that we have come to date that I know of is allowing people to allow an advocacy group of their choice to be able to look at that data and generate statistics out of it. But that's a different layer than inviting a community of people to all do their own statistical analysis.

Brad Power 50:57

I think that happens in rare diseases too, because there are people that are tight knit and passionate, and will do that sort of thing.

Deven McGraw 51:06

The rare cases are mostly what I'm talking about.

Deven McGraw 51:17

I'll get you the link to that guidance on the ability to access the underlying files, because it's kind of buried in an FAQ, and might be hard for people to find who don't know exactly where it is. So I'll get you that link and the link to the clarification that includes images as well. So that should be helpful. It won't have specimens, it will help you get the underlying files, hopefully.

Rick Stanton 51:46

Very interesting about the images. I had an IHC stain done on my primary tumor. And per request, I wanted to know if I had any evidence of tumor infiltrating lymphocytes, which might open up the possibility for immunotherapy. I asked that of City of Hope. My test result was, in these words, “zero to 5% TILS.” Period. I was like, “Well, are there any images? Could I look at the images?” I know images a little bit. “No, we don't take any images,” was their response. “We don't take any images.” Just, “The pathologist looked at it.” No images, zero to five. You're done. I was not satisfied. Is there anything that I could have done? Requested? It's not like I went in and knew, “Oh, there won't be any images.” Any comments?

Deven McGraw 53:05

Maybe because you asked for images specifically. Instead, maybe broaden the request a little bit, like, “Please give me the underlying data that informs this result.”

Rick Stanton 53:14

It was the pathologist’s eye.

Deven McGraw 53:17

This reminds me a bit of a story of a patient that I spoke to whose son had some sort of surgery on his arm that was done, you would think, through images. Like the surgeons looking at the image guiding the equipment in doing the fix, and then getting out, you would think that a history of medical care would include images taken of the steps in that process in order to document that the surgery was done correctly. Well, he had a very bad result. As a teenager, he now basically has a disability in his arm that probably will never go away. And when she asked for the images that were generated during the surgery, they said they didn't generate any. And that is a real problem when you're trying to get records because you just have this sense, “How could that possibly be good medical care if there wasn't documentation along the way of what was done?” But the unfortunate part is that the HIPAA rules are retrospective, and application only applies where you actually generated the documentation. It becomes this, “How could you not have generated documentation?” But if they say they didn't generate the documentation then, she was going to the Department of Health in the state where she lived and going, “How is it not malpractice to not generate documentation around this particular procedure?” Ultimately, you get the finger pointing, “It's their fault.” it's not a great answer. I always say, “Sometimes it's better to make friends than to use the legal screwdriver or crowbar because you might get a little bit less resistance.” But they sometimes find creative ways to tell you, and this was either their way of telling you that they have not given you something that they had, but they figured out an excuse or it just doesn't exist.

Richard Anders 55:26

Doesn't every modern pathology department make an image to send?

Brad Power 55:34

It's under 20% that actually get digitized.

Richard Anders 55:41

Sloan Kettering got in a huge amount of trouble, because they started a company that was using their image slide files. I imagine a lot of research institutions are trying to access and sell their slide data, and they probably are doing it by scanning it. What if they scan this file for some other purpose? Now they have the image. Is there a way to use that to get back the image, and say, “Well, if you're ever going to sell this slide for anybody, you better make sure you give it to me?”

Deven McGraw 56:18

It's always about “how long do they keep it?” If they made an image, and they kept that image, arguably, you have the right to it. If they didn't keep the image, but they made a copy of the image, then you have a right to that copy, as long as they've kept it. The tricky part is that sometimes this stuff disappears.

Richard Anders 56:42

A lot of these institutions do it because they want to monetize it, for example, if they can sell it to a pathology AI company or something. If they ever want to be able to do that, you can keep asking them. They may already be doing it, because one side of the institution doesn't know that the other side has spun off an AI company.

Deven McGraw 57:09

The proprietary interests of the company in monetizing that data is not a barrier to your getting it as long as it meets the designated record set definition. The fact that they have a secondary purpose for it does not obliterate how it was generated, and that it was generated for a clinical purpose, and they kept it.

Richard Anders 57:27

Or they created it a year later?

Deven McGraw 57:30

If they created it a year later, then you might have trouble connecting it to the clinical purpose that generated it. If they have a bunch of files, and then they generated something just for the

purpose of commercialization, and it was never a file that was ever intended to be used for clinical purposes, then you're going to have some trouble doing that. You could make a creative argument that what they created for the commercial purpose is data, and the data that fed into that was data that was part of the designated record set. So you have a right to at least what informed the creation of that second commercialized document. It's creative thinking wherever you can attach the underlying parts of this were used for clinical decision-making, and so therefore, I have a right to it. That's, that's what you’ve got to bank on.