Podcast Transcript

Let it Flow: Breaking Down Information Blocking

Date: February 24, 2021

Guest: Vimala Devassy, Kyle Gregory **Host:** Randall Rubenking

Run Time: 20:30

For questions and comments contact:

Vimala Devassy

Partner
Atlanta
T: 1.404.256.8243 | vdevassy@bakerlaw.com

Kyle Gregory

Associate
Atlanta
T: 1.404.459.4218 | kgregory@bakerlaw.com

Rubenking: Health information has long been trapped in electronic silos, which prevents the seamless exchange of information between stakeholders. Last year, the Department of Health and Human Services issued a number of sweeping regulations to improve interoperability among players in the healthcare space. These regulations will have significant impact on a broad cross section of the healthcare industry, requiring healthcare entities to rethink nearly every step of how they manage the flow of health information throughout its lifecycle. This task, while daunting, cannot be delayed.

I'm Randall Rubenking and you are listening to BakerHosts. On today's episode, we explore the specific details of the information blocking rules, which prohibits healthcare providers, health IT developers, and health information networks or exchanges, from engaging in practices that block the access, exchange, or use

of electronic health information. The penalties for engaging in such practices are serious.

Joining us today are partner Vimy Devassy and associate Kyle Gregory. Vimy and Kyle are members of our Healthcare Team, Digital Asset and Data Management practice group, as well as our newly formed Healthcare Technology team. This new team is focused on how innovation and technology are transforming the healthcare industry, and that digital health acumen is critical to success. Welcome, Vimy and Kyle.

Devassy: Thank you, Randall. We're excited to be here today.

Gregory: Thanks for having us, Randall.

Rubenking: Okay, now many of the most important compliance requirements, including the information blocking restrictions, become effective in April of this year. So this is a very timely topic. Vimy, let's start with you. What are the interoperability information blocking rules?

Devassy: Sure, so back on May 1, 2020, the Office of the National Coordinator, ONC, and CMS published two final rules. They were meant to implement the requirement of the 21st Century Cures Act, which was signed into law at the end of 2016. The ONC rule prohibits information blocking, and the compliance deadline was originally November, 2020. That was extended until April 5, 2021, due largely to the pandemic. The CMS rule expands the Medicare's conditions of participation, effective May 1, 2021, and what that requires is that hospitals provide electronic notification to a patient's primary care provider upon the patient's admission, transfer, or discharge in the hospital, which is known as an ADT notification, but we're going to be generally focusing on the ONC rule for the discussion today.

And, by and large, what information blocking means is when a provider engages in any practice that it knows to be unreasonable, and likely to interfere with access, exchange, or use of electronic health information. So, it's a really broad definition and some of the examples that ONC has provided as to what's information blocking are implementation of a blanket delay by a provider and the provision of test results, lab results, to patients, or radiology results, pathology results, which is relatively commonplace today.

Restrictions in contracts or in policies and procedures on the flow or access of health information. We're limiting the interoperability of your health IT, disabling or restricting capabilities within your EHR that prohibit sharing of electronic health information with other users of the system, or unreasonable fees that prevent access to health information. So, all things that are considered information blocking under the rules. And just quickly, I would note that the rules apply to what is called electronic health information, and so until October of 2022, electronic health information only includes what's known as USCDI data, which is a very narrow definition of data elements for things like clinician notes, immunizations, lab test results, allergies, medications, things like that.

After October 2022, unless it's delayed, it will include all electronic health information. Two other things we want to note really quickly is that information blocking is really a request driven process. ONC clarified in recent guidance that there's not a requirement to proactively make all EHI available. Instead, what information blocking really is, is that if you, if there's any delay in the release or availability of electronic health information, EHI, in response to a request for that information, it can't be deemed information blocking unless it meets one of eight specific exceptions. I'm going to pause here for a minute and just see if Kyle can help break down these exceptions for us.

Gregory: Yes, Vimy, these eight exceptions actually fall into two categories. First are the exceptions that involve not fulfilling a request due to the nature of the information being requested. So, these are exceptions where there's concern that fulfilling the request could cause potential harm or potentially fulfilling the request is infeasible or there are security concerns or privacy concerns associated with the information.

The second category of exceptions are those involved procedures for fulfilling requests to access exchange or use EHI. For example, if a provider receives a request for the access of EHI using a certain technology or requesting this EHI in a certain format that they potentially couldn't provide. The information blocking rule provides exceptions. If a provider could not respond in the way requested, they would not be violating the information blocking rule.

Devassy: Thank you, Kyle. In addition, we just want to note that information blocking violations really, they require, particularly when you're talking about a provider, it requires intent to block access to information in order for there to be a violation, and it's really, at this point, a complete base program. The Office of the Inspector General has not issued an enforcement rule related to information blocking yet for providers, it has done a proposed rule with regard to HIE's and Heath IT developers. But, it currently only has the power to refer providers to HHS for appropriate disincentives.

Rubenking: That's a great introduction. Well now, Kyle, what makes these new rules have such a large impact on the healthcare industry?

Gregory: The information blocking rules are such, represents such a paradigm shift because they require that actors, such as providers, health information exchanges, health IT developers, provide access exchange or use health, electronic health information. Unless the actor is prohibited from doing so under an existing law or one of the eight exceptions that we mentioned. While, under HIPPA, providers and other covered entities may share health data with other providers or payors. For certain limited purposes, such as treatment, payment, healthcare operation.

Under the information blocking rule, actors, such as providers, must share them unless one of the eight exceptions is met or some other law applies. And so what this really does is, traditionally, healthcare entities have been fairly loathed to share information for fear of violating HIPPA. This turns it on its head by

essentially requiring them to share information, upon request, to avoid violating the information blocking rules. So, it really does require healthcare providers and other entities regulated under the information blocking rule to rethink how they approach the sharing of health information. Which is really what the goal of ONC and CMS was, was to make health information more interoperable. Improving abilities for health systems, health technology, to talk to each other.

Rubenking: Okay, Kyle. Well now, with this new way of thinking about things, what should providers be doing to prepare for these new information blocking restrictions that take affect this April?

Gregory: So, we generally recommend that healthcare providers take a holistic approach, because there's a lot to tackle here. So, on one hand, you've got your administrative issues. Maybe you have policies or procedures that set forth certain practices that could potentially be considered information blocking. I know Vimy mentioned earlier, lab results. A lot of health systems have mandated delays, which really are not tied to any technical issue that delay the result of your lab test before you could see it out in maybe a patient portal or you get sent, you could get some of these results.

Working at your practices involving your patient portals generally or how you respond to patient requests for information. Looking at your policies on how you decide what third-party apps you want to connect to your electronic health system or your other healthcare information technology solutions. So there's definitely, from a policy side and procedure side, are we, recommend our clients take a close look at their policies and procedures that which address the sharing or exchange of information.

In addition to that, there's contractual issues here as well. As Vimy mentioned, information blocking can show up in contracts as well. So taking a look at your contracts with your health information technology vendors, and even for covered entities looking at your contracts and business associates to see how you put in place language, which would, or could potentially, limit or prohibit or create barriers to the exchange, access, and use of electronic health information.

Devassy: You know, I think one of the things that providers have been struggling with, in terms of the information blocking rules, is that for so long they have acted as a data guardian, or a data custodian, if you will, and they've worked so hard to really safeguard the privacy and security of their patient's health information, and so in some ways, this law I think runs a little counter intuitive to them on some of those types of issues.

And on top of that, one of the first oaths that a provider takes is to do no harm, and so I think for so long they have, one of their very important rules is to help to distill patient's anxiety about test results and sort of be there to help explain a lab result or provide context for it, so need to have a situation where we've kind of got this situation where patients are getting tremendous amounts of data so quickly and the provider is not necessarily there to kind of walk them through

that. I think that is something that's a little disconcerting to the provider community.

With that said, I think COVID, in some ways, has oddly been helpful in this situation, because it's helped, I think both on the provider's side and on the patient's side. It's really helped accelerate this notion that information, that knowledge is power, right?

That a better informed patient, can it truly really be a better partner in their own care, and so, you know how many of us have sat in front of a portal this past year, kind of clicking refresh and waiting and waiting for those COVID results to come in and providers have realized they can't, you know, particularly with COVID, there's no way to be able to get that information to patients as quickly as they need it. And so I think, that's, in some way, oddly helped to accelerate this paradigm shift and made this kind of almost become an easier norm for both providers and patients and it hasn't been, little bit oddly been a kind of a nice segue into where we are going with these information blocking regulations.

Gregory: Thank you, Vimy. Finally, take a look at your healthcare information technology solutions that you have in play. A lot of, because EHR vendors, along with other HIT vendors, have, are regulated under the information blocking rules. A lot of these vendors have been taking pretty aggressive steps to change their platform, to change settings available through their platforms that will help providers and their users comply with the information blocking rules.

Devassy: Kyle, you raised a great point, because I think one of the things that provider clients particularly are struggling with at this point is that, as much as EHR's have worked very hard to become certified and comply with these regulations. A number of them still lack some of the technical capabilities that enable providers to comply with these information blocking rules.

So, for example, on lab results, a number of the EHR's currently out there, currently don't have the ability to segment data at the level of granularity needed for a provider to comply with its obligations under the information blocking rules. For example, to prevent harm to a patient, which is a very high standard, it has to be, preventing harm to a patient, in that could potentially cause a threat to their health or safety or to their life, so. But if a provider truly feels that a lab result could cause harm to a patient, they're required under the information blocking rules, that's one of the exceptions that they can use to say okay, well this isn't information that we should not be making available.

You know unfortunately, a lot of the EHR's don't have that ability that would enable a provider to segment data in those situations and so if that is the case, it's really important to look at your EHR documentation and the information that they're providing you as what the capabilities are because that may help to elucidate core providers. In particular how they can comply with the information blocking rules and whether an exception might apply that they should be thinking about to protect their patients at large.

Rubenking: Well that does seem like a big paradigm shift in the way of thinking about this information. Now Vimy you said before this has been in the works since about 2016, do we know how the new Biden administration will affect these restrictions?

Devassy: That's a great question Randall and you hit the nail on the head. This, the 21st Century Cures Act was enacted in 2016 with strong bipartisan support. So, it was during you know President Obama's administration and so there at that time and there continues to be very strong support within President Biden's administration for advancing interoperability.

In fact, President Biden's you know most recent appointments to HHS and ONC are known to be strong advocates for interoperability. So, you know we certainly do not expect there to be anything that derails the advancement of these regulations going forward. I will say that the American Hospital Association is lobbying quite a bit to try to delay the rules once again with the understandable pressure that is already on providers due to the pandemic. Which has not you know in anyway lessened for the, you know since the rules were last delayed in November. So, they have asked that the rules be delayed until January 1, 2022, or until six months after the national emergency ends.

So, you know, the last time that ONC elected to delay the regulations within two days before the compliance deadline. So right around the end of October 2020. So you know if they were to delay it I think we would only see it very close to the next compliance deadline which is April 5, 2021 but if I were to have a crystal ball on this my prediction would be they would not necessarily delay again and the providers and all those subject to these rules should go ahead and get their house in order and be ready to comply as of April 5.

Rubenking: I see. One more question Kyle. What can we see coming on the horizon?

Gregory: So, we have a bit of a sense of where ONC and CMS are planning to go. In December of 2020 CMS actually released a new rule which would have expanded information sharing between payors and providers as kind of a complement to the rule that they released in May and the ONC information blocking rule also released in May. Now that regulation has actually been put on a regulatory freeze right now and we don't have a clear sense of when that will come, when that will be unfrozen. But the December 2020 CMS rule highlights that ONC does and CMS are not thinking of these rules as a vacuum.

There is going to need to be a lot of action from a lot of different HHS agencies to make interoperability or reality. Interoperability was one of the major drivers for the push to adoption of EHR systems which was included in the 2009 High Tech Act. So, this isn't something that is new and it is interesting to see how HHS is using a variety of different leverage from a variety of different agencies to help push this forward.

What I would expect to see in the short term is finally some regulation discussing how the information blocking disincentives apply to providers. Because as Vimy

mentioned earlier, right now we don't have clear guidance on what penalties are for providers who violate the information blocking regulations. So, in the short term that is something that we are all eagerly awaiting but longer term I expect to see some additional regulations that govern different relationships moving beyond the provider-patient or provider health information technology vendor relationships to kind of encompass all of the players in the healthcare eco system.

Rubenking: Okay, thank you very much Vimy and Kyle, you've given us a lot to think about.

Devassy: Thank you Randall, it was a pleasure speaking with you today,

Gregory: Thanks Randall, it was an absolute pleasure.

Rubenking: If you have any questions for Vimy or Kyle their contact information will be in the show notes. As always, thanks for listening to BakerHosts.