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Panel: Fraud and Abuse

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EMERGING TRENDS IN HEALTHCARE TECHNOLOGY:
FRAUD AND ABUSE PANEL

PANELISTS:
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Moderated by Deborah Farringer, Associate Dean of Belmont Law

[edited for reading]

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Casey Goggin: Next up, we have our second panel of the day, which is the Fraud and Abuse panel, and that will be moderated by Dean Deborah Farringer. Dean Farringer received her Bachelor's from the University of San Diego and her J.D. from Vanderbilt School of Law. Dean Farringer is the current Dean of Academic Affairs and the Director of Health Law Studies here at Belmont. At this time, please help me welcome Dean Farringer and she will introduce the rest of the panel.

Deborah Farringer: Thanks, Casey. Thanks so much to everyone for coming. We're really excited. You know, every year we rethink whether the third week of February is a good week to have this symposium, and I'm really glad for COVID right now because it would have been rather disastrous if we had spent all of this time planning for an in-person event and the snow had hit us. So, thanks everybody for coming. We're really excited that you're here and I'm really excited to share this panel today.

I'm going to let the panelists introduce themselves a little bit. I'll probably just give a little bit of a brief background for each of our presenters and then let them talk a little bit about their practice on a day-to day basis, what they do, and sort of where their practice is. So, I'm going to start out first, we've got Tony Hullender, who is to my left here, and Tony is the Deputy Attorney General for the Medicaid Fraud & Integrity Division for the Office of the Tennessee Attorney General. He's been in that position since 2016. And prior to that, he was in-house counsel for BlueCross BlueShield of Tennessee and worked at Miller Martin as a civil litigation attorney and was in the Army for 12 years attaining the rank of captain. He received his Bachelor's degree in English from the University of Georgia and graduated Order of the Coif from University of Tennessee College of Law. So Tony, welcome. Tell us a little bit about what you do on a day-to-day basis, Tony.

Tony Hullender: Good morning. Well, we have a very narrow mission. We call ourselves "MFID" so we don't have to use that long name. But we have a narrow mission: we civilly enforce the Tennessee Medicaid False Claims Act[1], which is patterned after the federal False Claims Act[2]. So, we are only dealing with Medicaid fraud, unlike the Federal False Claims Act. It covers a lot of different kinds of fraud. We focus solely on Medicaid fraud and solely on providers and solely civil. So, we basically have two kinds of cases. One are qui tam cases which a whistleblower files a case under seal and then we decide whether Tennessee is going to intervene or not.

[1] Tennessee Medicaid False Claims Act, TENN. CODE ANN. §§ 71-5-181 *et seq*.
[2] False Claims Act, 31 U.S.C. §§ 3729-3733.

And then the non-whistleblower cases, typically are referred to us from TennCare. But they usually get them from one of their three MCOs, managed care organizations, BlueCare, United, Amerigroup, which all have their own fraud divisions. If they see potential TennCare fraud, they refer it to TennCare. TennCare does a preliminary investigation. If they think it has merit, they refer it to us for civil investigation and then they refer it to TBI for criminal investigation.

Deborah Farringer: Alright. Thank you. Okay, next we've got Lisa Rivera. So, Lisa is currently a member at Bass, Berry, & Sims and focuses on advising healthcare providers and pharmaceutical manufacturers, medical device companies, on civil and criminal matters. So, she's going to tell us a little bit about her practice. She was formerly Assistant United States Attorney for the U.S. Attorney's Office for the Middle District of Tennessee where she was the civil and criminal Healthcare Fraud Coordinator and has also worked with Medicaid Fraud Control Unit with the TBI. She was an Assistant U.S. Attorney in Puerto Rico and a state prosecutor in Florida, and also has a commercial litigation defense practice background. She got her J.D. from the University of Memphis and a Bachelor of Science from Tennessee Tech University. So, tell us, Lisa, about sort of your day-to-day.

Lisa Rivera: Hi, good morning. Thanks for having me. Really, my focus is in civil, potential civil and criminal healthcare enforcement by state and federal authorities, primarily False Claims Act investigative requests that are served on various types of healthcare providers, from large healthcare systems to individual private practices, device manufacturers and folks that use those devices, look in the government review for any sort of anti-kickback concerns and physician Stark concerns. So, it could be at any level. It could be the Board of Pharmacy. It could be state. It could be Tony; it could be Ellen, for a variety of issues. And, also, a lot of internal investigations and proactive compliance counseling with clients on a regular basis. As we all know, this is a highly regulated industry and it's constantly evolving and changing, which makes it very challenging and exciting practice area of law. And, so, it's always interesting for sure. But that's really it on a day-to-day basis.

Deborah Farringer: Alright. Thanks. Our next panelist is Amy Leopard. She is a partner at Bradley Arant Boult Cummings. And her practice focuses primarily on health IT and regulatory compliance and she's a certified Information Privacy Professional and formerly chair of the AHLA Health IT Practice Group. So, she's going to tell us a little bit about her practice with over 25 years in

health care. She graduated high honors from Auburn University and earned her master's degree from the University of Alabama at Birmingham and has her J.D. from Case Western Reserve University, where she graduated *cum laude*, and was the Editor in Chief of the Health Matrix Journal Law-Medicine, which is one of the, a great health law journal out there that does a lot of, publishes a lot of interesting work. Amy, tell us a little bit about your day to day.

Amy Leopard: Yeah, hi Debbie. Good morning everybody. And, yeah, so when I was in law school, much like many of your students, I knew I wanted to be a health lawyer. And I came to law school from hospital administration. So, one of the things I did when I was in law school was intern in the Justice Department, and that kind of started off a 10-year career in Cleveland as a fraud and abuse lawyer. I came to Bradley about 9 years ago to head up the Health Information and Technology Practice. So, that's 90 plus percent of what I do every day, whether that's on the fraud and abuse side, on the payment side, on the I procurement, looking at HIPAA. Right now, a lot of cybersecurity incident response is going on in the hospital communities. But also looking at technology, technology transfer, and artificial intelligence. So, it's a lot of fun. I think my role today on the panel is more compliance oriented than the rest of the panel.

Deborah Farringer: Alright. Thank you. And our final panelist today is Ellen McIntyre. She's an Assistant U.S. Attorney here in Nashville with the Middle District of Tennessee. She's been there since 2003 and she handles various cases, primarily on the False Claims Act and other health fraud on the civil and criminal side. And before she was an AUSA, she served as a Senior Trial Attorney for the Justice Department's Civil Rights Division and a staff attorney at the Southern Poverty Law Center. She graduated *cum laude* from the University of Pennsylvania and received her J.D. from Columbia Law. So, Ellen, talk to us a little bit about your practice.

Ellen McIntyre: Thank you so much, Deborah, for having me today. So, I am the Affirmative Civil Enforcement Coordinator for the U.S. Attorney's Office here in the Middle District. And what that means is, essentially, I help coordinate the team of people who do the plaintiff's side work on behalf of U.S. Most of that work in our office, I would say, maybe 90%, 85-90%, is under the False Claims Act. And, of that work, you know, the vast majority is healthcare fraud, in particular, because obviously we are a healthcare fraud center. And, you know, sorry to say it, but there's a lot of healthcare fraud in this district, right? So, anyway, that's what we pursue, and

we have big team that do it. And I think that we are one of the leading units in the country. So, you know, we have a lot of cases cover, that run the gamut in terms of different types of healthcare fraud. And, you know, we try to obviously do a great enforcement job for the district.

Deborah Farringer: Alright. Thanks. So, we're going to kick it off here by asking some questions about fraud and abuse trends. So, I'm curious, first we'll talk maybe to our practitioners and then we'll talk with our government attorneys here, about what fraud, waste, and abuse trends you're seeing now as a result of the pandemic that you didn't see prior. So, after COVID kind of hit us in March of last year, what are any new trends, what are you seeing now from a fraud and abuse perspective that's maybe new or different? Lisa, let's start with you.

Lisa Rivera: Well, so, in my experience there were a momentary lull in investigations that were ongoing and sort of in the pipeline, initially. And then, I think the government adjusted and began picking back up speed, having to do things virtual. I mean, that's not something the government would typically like to do when gathering up evidence and judging credibility of witnesses and evaluating their cases. But they decided, they're going to go forward and do that, they weren't going to postpone it any longer. And so, that picked up speed again.

We've all had to adjust in terms of responding by Zoom, having some back-and-forth presentations with the government, which we typically do in a lot of cases, having witnesses and clients interviewed over the internet with government counsel. We've all had to adjust in order to continue in working in those investigations. I think that from an enforcement standpoint, you saw initially, and still do occasionally, a headline about sort of what I would consider more low hanging fruit related to COVID funding where you know, somebody bought a Maserati with those funds and provided fraudulent representations about perhaps, COVID vaccines or other remedies. So, but I think eventually it will, I think we view this as sort of a perfect storm in an already highly regulated industry. I mean, just when you thought it really couldn't become more scrutinized. It looks like the perfect storm for that because you have an unprecedented amount of money that was earmarked and distributed to the healthcare industry, unlike before, any time before.

And at the same time, when that money is being received, I mean provider and healthcare organizations' hair is on fire. And they're dealing with a crisis and you also had as part of that, sort of

evolving government guidance, or still trying to determine what the guidance would be with respect to the funds, as well as the applications and type of information that's requested for those funds. And then you're going to have, because of the amount of money, guaranteed retrospective scrutiny over the eligibility for the funding, the use of the funds, and the certifications around entitlement and representations to the government about the funding. So, I think that that is going to be something that the government will be gearing up for. Those sort of complex matters are not going to [inaudible] immediately, but I think as time goes by, that's what we're gearing up for and that's what we anticipate from the government.

Deborah Farringer: Alright. Thanks. So, Amy, what about you on the technology side? What kinds of things are you seeing from your clients in terms of new or different issues that are coming about as a result of the pandemic that you feel like has really started to become really commonplace in your office?

Amy Leopard: Well, I think like Lisa, a lot of it is the provider relief payments and the, you know, let's just recognize that the government funding was critical to keep our industry running. Right? But there are strings attached, and so, you know, thankfully when HHS started to promulgate some of these rules they decided that you, providers would have a little extra time to reject the additional terms and conditions that were being imposed during all of the chaos. And so, what you've seen is, are clients that have, you know, good compliance programs have had to do that, and, you know, reject those terms and sometimes return the money. And so, hopefully, if you've got that documentation and some grace from the government to, you know, have time to take a more organized approach to certifications that were made during, you know, what now in hindsight we see was pure chaos. That has been extremely helpful.

Those same certifications come into play on technology as providers have to attest to CMS, to Medicare, that they are using updated technology to be eligible for the EHR incentive programs. And, we've seen just within the last month, where the Justice Department has begun to prosecute an EHR vendor, kind of on a new theory goes beyond some of the theories in the past under the False Claims Act against vendors that, you know, didn't have the security that's required by the EHR rules, or failed to provide a functionality that's required, and then now going into whether or not EHR technology vendors are paying kickbacks in the form of Kentucky Derby and other kind of boondoggles, so to speak. So it's

a real evolving climate right now both on the technology side and on the provider side. But I think paying attention to those attestations, recognizing that there are statutes for False Claims Act and false attestation liability. So maintaining that compliance documentation is key.

Deborah Farringer: Yeah, it sounds like, the both of you, it's really a little bit of you're not quite sure what's going to happen when things sort of all shake out, right? It's difficult to tell at this point in time because unlike in the past when you're sort of aware of Stark Anti-kickback False Claims Act what the rules are this is sort of a whole new set of regulations, a whole new set of compliance concerns. And so it's a little bit difficult to try and figure out what exactly the challenges are going to be before we before we hit them.

So, Tony and Ellen, from your perspective what sorts of things are happening in your office in terms of what you're focused on right now, for purposes of post-pandemic fraud and abuse? You obviously, both the Department of Justice and I think the Medicaid fraud unit, had things that they were focused on in the pandemic. How has that shifted in the last year as things have sort of changed globally here?

Ellen McIntyre: Well thanks Deborah. So I'm of course going to be talking about things that are public, because I can't talk about non-public things that are under investigation, and same for Tony. But I think that there we're going to see different types of schemes and there have already been some, you know, there's been a number of public things that have that we can look at publicly.

So the first type I wanted to talk about was kind of like classic criminal schemes that have arisen in the pandemic in terms of healthcare fraud. Just this month actually, in February, the HHS issued a fraud alert actually to the public.[3] In other words, not to providers but to the public, to warn the public about types of COVID-related schemes, like people calling and saying "We'll give you a vaccine or we'll give you, you know, something related to the pandemic if you give us your Medicare prescription number" kind of thing. That's really important that the public not fall for those total scams.

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[3] Press Release, DEPT. OF HEALTH AND HUMAN SERVS. OFF. OF INSPECTOR GEN., FEDERAL AGENCIES WARN OF EMERGING FRAUD SCHEMES RELATED TO COVID-19 VACCINES (December 21, 2020), https://oig.hhs.gov/documents/coronavirus/245/Vaccine-Fraud-PSA.pdf

And then also there have been some indictments already, there's even been like some guilty pleas. The kinds that I've seen are there are indictments of ads for vaccines that cannot be verified as real; in other words, people are marketing a fake product that could reel people in, in this climate of fear that we live in. Of course we've all seen the ads about hoarding or price gouging of personal protective equipment, and then there is also one of the things that you know some of the defense lawyers here talked about is there could potentially be fraudulent bank loans seeking CARES Act relief or other kind of advance payments under the Medicare program due to the pandemic. And so whether that's a fraudulent bank loan or whether that's you know a certification 'hat people don't live up to, that could fall into the realm of possibly criminal, possibly civil, depending upon what the conduct turns out to be.

In the terms of like the civil stuff that we might end up seeing as a result of this, obviously you could see a misuse of COVID relief money which again could be from Medicare or from the CARES Act. That money, if it's from the Medicare program, is intended to be spent on healthcare. And so if recipients of 'hose funds don't spend it on healthcare or if they've misrepresented something such as like having ghost employees'(you know, you've seen this, you've see this in the media anyway), that what if somebody says well we've got 100 employees and we need those funds to continue paying them, but actually maybe they've laid off those employees and they don't bring them back, and they use the money for something else–all of that is obviously fair game in terms of being investigated.

Another thing that, I don't know how much it's been in the press, but I think there is a potential for additional worthless services investigations in the nursing home, skilled nursing facility context because even though obviously the government can't get into those facilities at this moment in time, there may be uncovered that some of these spread in the facilities could be linked to poor infection control, that sort of thing. And so down the road that is something that might come up around the country and we'll be looking in those in those areas.

Deborah Farringer: Alright, thanks. Tony what about you from the Medicaid side and TennCare? From your perspective what have you guys been either seeing that's public, you can talk about, over the last year or anticipate is going to become a new area that's really going to be a focus for you?

Tony Hullender: First of all, I think Lisa mentioned this initially there was a real lull on all sides. So for a long time we've just been catching up on our non-COVID related cases. I think Ellen mentioned, the last thing she mentioned she said that's something she anticipates might happen, and I think that's where we are in terms of what I think of sort of classic provider fraud. And other things we talked about misuse of CARES funds and that sort of thing, like consumer fraud you know selling a fake vaccine, that's really not what my division does. You know, we're more about a physician files a claim for payment and it's false because he didn't do it or he up-coded it or something like that, and for those kinds of things I think it's a little early' My office isn't seeing any COVID-related fraud like that yet. It will probably start with those TennCare managed care organizations. And I've talked to those fraud department of these MCOs and they're not seeing it yet in Tennessee, but they're looking. They're concerned, if for no other reason, because it's new. And whenever there's something new and there's a high volume it can take a while for everyone to figure out what's going on. You can be pretty sure there's going to be a small percentage of providers that will do something that they shouldn't do.

A couple things that they're looking for which are kind of traditional but not in the COVID-19 context: they're going to be looking at the tests because there's so many of them, they're going to be looking for providers that bill for tests they didn't do, they'll be looking for providers that bill for tests that weren't medically necessary, that one might be kind of hard given the pandemic. Another one I found interesting that one of the heads of the fraud Department from one of the MCOs told me is they're looking at add-on services. I think they've seen that in some other states where someone's there for COVID testing or COVID treatment and the provider adds on test that, at least from the government standpoint, are not medically necessary. Genetic testing for something that was mentioned, and there's a type of pulmonary test (I wrote it down because I don't know what it is) respiratory pathogen panel. That must be happening in another state because it's sort of on the radar.

Deborah Farringer: Thanks, that's a good segue, because one of the things you mentioned is we're sort of waiting and watching. And I think one of the things that's really been on the uptick, they talked about it in the first panel a little bit, is the use of telemedicine, right, the increased use of telemedicine during the pandemic. Obviously one of the things that's really been different in terms of telemedicine is the total relaxing of the rules. Telemedicine was previously relatively restrictive at least from a Medicare perspective in terms of

Medicare payments only for certain rural providers and only for certain specific sites and that sort of thing, and all of those have been waived now.[4] So with the increased use of telemedicine, how do you feel like that is impacting the fraud and abuse analysis and what's your advice to physicians regarding what to do now the interim when everything seems to be the Wild West? And then how to anticipate what might happen later when we go back to an end to the public health emergency and there is some reinvigoration of some rules here. Do we have somebody? Amy, do you want to start there?

Amy Leopard: Sure, yeah so that expansion of benefits has had a huge impact on the delivery system. The relaxation of the HIPAA rules has helped with vendor contracting, the ability to use cell phones on both sides, and allowing facilities to provide their medical staff with a telemedicine platform–all of these things have had an immediate public health benefit. I listened in on your panel this morning and you can hear just over and over again the public health tool that telemedicine has provided in the middle of the storm. Keeping up with those challenges and just where all of the changes have been made has been difficult. I mean that's kind of settled down a bit, but the hard part is going to be when the party is over. We saw that just recently in looking at a telemedicine program between Tennessee and Mississippi that, after all the state medical boards had relaxed licensing requirements across state lines with great fanfare last year, Mississippi quietly rescinded their rule and now requires a license.[5]

And so, we're in Tennessee, we might be aware of that you need to have a license to telemedicine with Mississippi residents but do providers in Maine know that? That's what I see is there could be some gotcha moments, and hopefully providers will not so much be in the crosshairs as we take down the waivers but there there's some type of grace period

Deborah Farringer: Lisa what about you? What are you seeing from your clients that are sort of similar, how are you advising your clients right now on telemedicine, and how to be cautious because we're in this in-between moment?

Lisa Rivera: Yeah, there's this, I think, an initial feeling of, hey, the government is here to, as Amy put it, in this public health crisis the government's here to help and lend support both financially and in in relaxing some of the requirements that might otherwise be in

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[4] 42 U.S.C. § 1395 *et seq*.

[5] MISS. CODE ANN. § 73-25-34(2) (1972, As amended); CODE MISS. R. 30-026-2635, RULE 5.2 (2021)

place because we just want to get patients treated. We want to not have, as you know, too many barriers in the system for patient care right now in this crisis. Frankly, that's not going to be the perspective of the government later when they're coming back to look at what was happening during this time period.

When you think about large health systems right now dealing with all of the COVID issues, stopping many procedures, moving employees around within a system to render aid for certain issues and certain health concerns, and sort of transitioning to telehealth, I think CMS issued something that said that there was an 11,000% increase in telehealth services post-pandemic. That's a lot. That's a lot of money and that is just not going to go unreviewed going forward. They're coming! So I think for clients right now understanding that there's so much on their plate and so many things in the air. If you think about it, a lot of clients will have sort of a central command center for COVID because there's so many plates in the error related to responding to COVID. You know, pulling from here means there's an issue over there, but you're trying to jump on a fire that's happening in this area, and so you pull your resources from other areas within your enterprise. So I think that trying to help clients understand and document the reasons that exist right now for why they're going what they're doing is going to become very important when the government is later looking at telehealth services and others with skepticism, because of the numbers, and a different lens than maybe health care providers are reviewing right now.

In September of 2020, DOJ has a big nationwide takedown every year, and in September 2020 they had theirs and it was primarily related to telehealth enforcement. I think that the allegations around the alleged telehealth fraud was about $4.5 billion in fraudulent billing related to telehealth, and that's pre-pandemic. I couldn't tell you about each and every case because that's a coordinated effort, those cases aren't all related to one another, but the number that the government had in their press release related to telehealth services and frankly I think the majority of that may not necessarily be post-pandemic.

Deborah Farringer: Thanks! So Ellen and Tony, I want you to kind of get in here and we also just had a question from the audience as well that was something I was thinking about. The usual tools, right, and oftentimes what defense counsel will tell their clients is just make sure you're not an outlier. Watch your data to make sure you're not doing anything that sort of gets you on the radar. And with the increase that Lisa just talked about, so with the increase in

telehealth at 11,000% I think is what she said, how is that data is going to be used? Will it be used? Should that be something that providers pay attention to? Can you talk to us just a little bit about how the government might be thinking about this interim time period.

Tony Hullender: Yeah, this is so new that I've not had any cases that were based on telehealth but I think there is going to be some similarities. My experience tells me, when you have something this new, two things happen: One, there's a tiny percentage of providers that will spend some time figuring out a way to defraud TennCare with this new scenario, and two, there's going to be a period of time where there's confusion about the rules, the regs, how it all works. And I don't know if there would be an official grace period, but I think there'll at least be a practical grace period where it's going to be pretty hard, unless somebody billed for services the' didn't do, it's going to be pretty hard to prove fraud as everybody's trying to get this done.

In terms of spotting it, I think it'll still be, we'll still use the same tools. I'm not a data analyst but I work with a lot of data analysts, and I think they will still be looking at 'he data but it's going to take them a while to figure out how to massage that and how to interpret it. But like you said, they're still going to look for outliers, it just may be the outlier number is a lot higher than you would've thought because the baseline is low. I told you I talked to the chief of the fraud division of one of the TennCare MCOs, and for example, he said they've already seen some labs that they thought were outliers, but then when they dug into it there were reasons, non-fraudulent reasons, for it. One of them had an exclusive contract with very large health plan. Another happened to have a lot of customers in an area that was hit harder than most by the pandemic.

So yeah, I think there may be some challenges but I still think it would be the same sort of thing. You're right about, you know, providers should try to not be outliers. I would take it a step further and say if you're going to be an outlier, well even if you're not an outlier, know your codes, the codes that you're using, CPT codes. If you're using one that gets you a lot of revenue, pay particular attention to that Don't take someone else's word for it, physically read the description of the code. And then I would say focus on medical necessity, make sure that what you're doing is medically necessary. And if you do those two things, I think more often than not you're going to be okay.

Deborah Farringer: Thanks. Ellen, what about you? [inaudible]

Ellen McIntyre: Thanks. Well, I think some of this is kind of common sense. If you have a provider that is billing this many in-person visits and then they shift to telehealth when there's the waiver during the pandemic, and you see that the total numbers add up to the same – that is not going to be this big red light in our mind I would think. But if you see a situation in which they were only billing this many in-person visits and then their telehealth visits go up like to the roof, I mean that would be the kind of thing that would look suspicious, potentially, and might be looked into.

In general, although I don't think people have talked too much about the specifics of telehealth, I thought it might be helpful if I could tell a few of the government's concerns in this area. Lisa had mentioned that there was a prior telehealth takedown and that's correct. That involved a lot of possibly criminal kinds of conduct in which you saw pre-pandemic use of telehealth in a way that there was not really a legitimate service being provided. Often you would have some improper marketing that would get maybe by leads of customers and then pay a kickback to a physician to either sign an order for DME or genetic testing, or maybe they don't have any visit at all. So we're not really talking about the legitimate shift that, to some extent, is obviously underway right now, but before that you had different kinds of abuse of telemedicine and those could be kickback relationships and there could be resulting prescriptions for non-medically necessary items.

The other area I wanted to mention briefly was electronic health records cases. There are two different types of schemes schools in this area. Amy alluded to one of them and she was referring to this $18 million settlement that was announced from in January of 2021 from the district of Massachusetts.[6] That did involve traditional kickbacks in the sense of the company allegedly was marketing their electronic health systems to either existing customers or prospective customers by giving them improper kinds of kickbacks, like tickets to these really expensive items, luxury things, just classic stuff. The other type of arrangement which we've seen in this district in the Inform Diagnostics case is when there was actual provision of reduced-cost electronic healthcare record systems, or linked-in technology to assist with those systems – we've

[6] Press Release, DEPT. OF JUSTICE OFFICE OF PUB. AFFAIRS, ELECTRONIC HEALTH RECORDS TECHNOLOGY VENDOR TO PAY $18.25 MILLION TO RESOLVE KICKBACK ALLEGATIONS (Jan. 28, 2021).

seen that in our district and that resulted in a $63 million settlement.[7] But all of these are kind of part and parcel of what goes into what the government looks at in the telemedicine field so far, and of course that may change if there is abuse of the current telemedicine increase that's been going on.

Deborah Farringer: Yeah, let's talk about that for a second. Interesting that you point out electronic health records since our theme here is technology. Amy and Lisa, that was an area of focus that the Department of Justice has previously, last year pre-COVID, had ramped up and said we're going to start paying attention to more of this. We were seeing more certification cases when it came to EHR certification, we were seeing an increase – there actually has been a few instances of EHR vendors being subjected to False Claims Act violations or settlements in connection with False Claims Act for certain hard-coding in connection with meaningful use payments. As you have shifted focuses here and the pandemic has distracted providers with other things, these new things to be worrying about, how are you still keeping your clients aware of what was already-existing fraud that has been the focus of the Department of Justice and making sure that people are still keeping these things in mind? Have things shifted so much people have forgotten about it? How are you making sure that your clients are keeping on track with this previous fraud concerns as well?

Amy Leopard: They haven't forgotten about it. They've probably developed a better understanding that they should be worried about it, as they see what's going on in the enforcement would. And so I guess I'm seeing more clients each year who ask, "Is this compliance documentation that I have sufficient for me to make this certification?" Like getting a second opinion on whether or not all the 'yes are dotted and T's are crossed, and that seems to be each year, more and more people, as they're sitting down to sign that certification and make that, you know, "I swear to the federal government that everything is true, accurate, and complete," they start to get hypertensive. And when that happens, they're looking for someone to kind of come in and help them understand, is my compliance documentation sufficient. I've seen a lot more of that each year, so I think the awareness is there.

Lisa Rivera' Yeah, I think that's right. I think it's been an incredibly stressful year for these organizations having to switch gears and decide, after patient care, under these circumstances what is the next

[7] Press Release, DEPT. OF JUSTICE OFFICE OF PUB. AFFAIRS, PATHOLOGY LABORATORY AGREES TO PAY $63.5 MILLION FOR PROVIDING ILLEGAL INDUCEMENTS TO REFERRING PHYSICIANS (Jan. 30, 2019).

fire we should put out? I don't know how well-reported it was but a lot of health systems (maybe you mentioned this earlier, Amy, or maybe it was in the earlier panel) but there was a real cybersecurity scare that was going on with a lot of health systems in the country while they were trying to respond to COVID. It's just really unfortunate that that happened but it impacted their abilities to communicate with one another because of the measures that they had to take during that time. It was very concerning so that's a regular concern, you have those kinds of things in place already but your system is constantly being pinged, I mean thousands of times a day, looking for an open window by people that want to do it harm. And that's just a normal day. So with all of this going on and having to adjust to protecting their information while they're trying to adjust to the COVID crisis that has evolved really throughout the year from time to time has been very stressful.

I think that their compliance teams, the communications about that have been more regular in trying to keep all the trains running on time and stay within the guardrails at the same time, just like they would typically do. But it has been a very stressful year to try to make sure that there is no ball dropped anywhere during the middle of all that. And talking to them about it and documenting things that are happening, because when somebody comes to call and ask about it two years from now or eighteen months from now, or whistleblower files a suit about some portion of any of that, they're going to have to reflect on, from two years earlier and understand with everything that was happening at that time, what were the considerations that that were impactful for any particular decision-making or the ability to refute what is being alleged is going to be it's just going to be so important because they just have so many things going on. People move on, they need to document to the extent that they can based on the information that that they know right now that supports the decision-making around all those issues.

Deborah Farringer: Thank you. So, documentation, documentation, documentation–that's what I'm hearing. Let's switch gears here a little 'it and talk about…we've been talking about COVID and telemedicine waivers. Simultaneously, sort of ongoing with this, was a push already to try and ease up some of the restrictions under Stark and anti-kickback, and we had some Stark sanctions that have been waived during the COVID pandemic.[8] Talk

[8] Social Security Act § 1135; 42 U.S.C. § 1320b-5; CMS, BLANKET WAIVERS OF SECTION 1877(G) OF THE SOCIAL SECURITY ACT DUE TO DECLARATION OF COVID-19 OUTBREAK IN THE UNITED STATES AS A NATIONAL EMERGENCY

to me a little bit about those changes in terms of some easing of the Stark regulations, and then also proposed regulations for purposes of trying to make Stark more flexible. How has that sort of altered your practice in any way? How has it changed how you advise your clients? Have clients been receptive to that or is it like there's just so much going on they can't even focus on any one of these things as an advantage or disadvantage? Lisa I'll probably start with you, just cause (I know you spoke last) but this probably gets to the heart of what you do day-to-day'

Lisa Rivera: So I'll tell you, our healthcare clients–I mean we had a crack team trying to gather all of this information and understand what the guardrails would be going forward based on the information available and what would that look like. Unlike telehealth where we, as a panel talked about how we think telehealth is probably the horse is out of the barn there, we don't really see it reverting back to the way it was even from a government perspective, it's just how is it going to look, what's it going to look like going forward?

But a lot of the Stark and the other issues where waivers have been issued, I think the government is intending to revert back in a large way. Look, the government doesn't like to bring cases where the rule was one way Friday and by Tuesday you weren't back in line, I mean that's not the kind of case I'm talking about. But they are going to be looking at how providers do transition, if they moved away from it in the first place, whether or not they still did so in a compliant way and going forward how that looks. I think it's going to be very difficult to argue a justification, as more time is removed from COVID when the waiver time period has passed, to justify not getting back on track. And again, you know, I don't think the government is looking for those kinds of close-call cases but a' the same time I don't think that providers can be comfortable thinking that that they're going to be able to justify that moving forward even after the storm is over.

Deborah Farringer: Amy, do you have any thoughts on that from your perspective, for your clients?

Amy Leopard: Yeah, I think providers need to remember to document that they met all of the other requirements that were not waived' right? Because that's going to shine a big light on things. But as far as the waivers that we had, those waivers have permitted hospitals to pay hazard pay to physicians, to provide free on-site

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(March 1, 2020), https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.

child care to doctors that are working long hours, to rent medical office space where there's surge capacity needed for ambulatory, the share PPE with referral sources, to make loans to specialists who were hard hit when elective procedures were paused and they want to retain this anesthesia group. So there's a great deal of flexibility there but you still need to, I think as Ellen said, have commo' sense right? If you're providing something under a waiver and the rationale for that waiver has started to dissipate, it's really time to start getting your exit plan in place. And you really should enter these waivers with an exit plan so that you're level-setting expectations that this benefit is tied to the COVID pandemic and it is not going to go on forever and you can easily unwind them.

Lisa Rivera: Yeah, and Debbie the language in the waivers require otherwise fraud and abuse concerns and considerations,[9] so you can't just throw everything to the wind. There are still the straight and narrow that has to be followed in order for those waivers to really be valid, or at least arguably from the government's perspective.

Deborah Farringer: Great, thanks. Ellen and Tony, do you have– obviously, Tony, you don't deal with Stark specifically, that's a federal law or the anti-kickback statute but from a perspective of thinking through a post-waiver environment, it can't be a light switch probably, right? It's going to have to be some sort of a dial where things are sort of dialed back in. From your perspective how is it that the government is thinking through what life might look like post-pandemic?

Ton' Hullender: And you're right there are scenarios where we're involved in Stark and anti-kickback, but not enough that I've dug into these waivers. I figured by the time I have another one of those cases, the waivers will be gone, so I haven't given that much thought.

Ellen McIntyre: Yeah I don't have much to add either on that' but I mean, also we're in a new administration, all these things are up in the air, but I think that the right note is sort of what the defense counsel struck about you've got to be careful with this stuff.

Tony Hullender: By the way Deborah, did you say somebody had sent in a question or did we cover that?

Deborah Farringer: I think we've had–I was going to ask Paige, too. I think we had one specific question, then maybe another question that might have been posed to our director here. One was on how might the government, federal or state, be employing data

[9] *See* 42 U.S.C. § 1395nn.

mining to look for some of the alleged COVID add-on test fraud? So to what extent are you monitoring this and thinking through certification and some of the COVID add-ons that are part of the federal dollars?

Tony Hullender: Yeah, we don't do our own data analysis. That starts with those MCOs that I keep mentioning, cause all three of those MCOs are huge and they have their commercial business too. So I'm sure they have a room full of brilliant data analysts that come up with different algorithms to try to find that sort of thing, but I don't I'm not privy to exactly what they're doing right now. And TennCare here has a bunch of data analysts as well, and they do some of that. They do a lot of other things with it too, but I'm sure they're looking at if you decode the diagnostic codes and doing peer comparisons, the same sort of things we do with other fraud schemes.

Deborah Farringer: Ellen , what about you?

Ellen McIntyre: I would just generally say that the DOJ and the US Attorney's offices do ongoing data analysis, and so we're just on the lookout for things and whether they corroborate allegations or whether we find things trends of concern. But I can't really tell you specifics about what we do in that regard. I also think it's worth noting that there's also there's always whistleblowers who could report on specific things going on if they have concerns, and so those end up coming to us at some point often. And I do think that the potential for upcoding exists in the pandemic because even just the nature of telehealth–some things are less likely to be happening, right? You're not going to have a physical exam, the visits might be shorter. That's my personal experience, there's just different things and I think the coding has to be linked to what's really occurring, obviously, what's appropriate.

Tony Hullender: Yeah, for example, good that you mentioned the whistleblower, I meant to do that as well. For example, and I don't know what the deal is with genetic testing, why they're looking for genetic testing as an add-on, but they could have a whistleblower come in and say, "Hey, this doctor that I work for is putting genetic testing on every single COVID person that comes in here." And that could alert the MCO or TennCare that, say, well let's run a check on all the primary care providers in Tennessee. How many of them are using that code for genetic testing? If a whole bunch of them were using it, they'll still look at it but there may be a valid reason if nobody else is doing it, then that person is probably going to have their medical records reviewed.

Deborah Farringer: Yeah, thank you so much. It sounds like a lot of what is going on is that, or there is an increase in data but that the idea of an outlier is actually not changing at all, right? That there are still going to be things that are present in the data that are out there that there are going to be general upticks, and then there will be individuals probably who are beyond what should be the normal or the general. And so probably all of the same advice that was given before should be given now in the sense that everything needs to be justified and documented, and that you need to have appropriate justification for exactly why you are doing everything, and that we are going to continue to watch the data in the same way we did before.

Well we're about out of time. Thank you so much to the panel, I really appreciate all of you. This has been a really helpful panel from my perspective. I think it's always interesting to think through. I would love to have all of us back in a year, because I think it would be a very different discussion. We're in the middle of it right now, and so I think it would be interesting to be able to have the same discussion a year from now and figure out maybe what we didn't know now that we will know then.

Tony Hullender: Maybe we can be in person next year. Does this mean I don't get my Belmont coffee mug?

Deborah Farringer: Oh we will be sending it, no worries. It's just coming in the mail.

Amy Leopard: Maybe there will be some rest for the weary by then.

Deborah Farringer: I hope, I hope. Thank you so much all of you.