Fox Rothschild Podcast

The Presumption of Innocence Podcast Series: Episode 15

Compliance: On the Minds of In-House Counsel

Featuring Matthew Adams of Fox Rothschild LLP and Ricardo SolanoCareOne

Adams: Hi everyone and welcome back to "The Presumption of Innocence," a podcast brought to you by the White-Collar Criminal Defense and Regulatory Compliance Practice at Fox Rothschild. I'm your host, Matt Adams, and I have the great pleasure of being joined by my friend, Ricardo Solano, today. Ricardo is the Executive Vice President and Chief Legal Officer at CareOne.

Ricardo, thanks so much for being with us today. How are you doing?

Solano: Good, Matt, how are you? Good afternoon to you and thank you for having me. Looking forward to our conversation.

Adams: Yeah, me too. I'm so glad to have you. Ricardo, you come from such a diverse background: You were a federal and state prosecutor, you did two tours of duty in private practice. Now you've jumped into your in-house role in what I will characterize as a highly regulated health care industry business and a large one at that. What was the biggest shock to your system jumping into that, mindful that we're really talking regulatory compliance today?

Solano: The biggest shock to the system -- and I've done a lot of work in the health care space and for CareOne prior to coming in as in-house counsel -- but on the in-house counsel side, on a day-in and day-out basis, how much the regulations, the law, the policies of the Department of Justice, of CMS, you name it, state regulators, impact the decision-making within the company.

Things that you never go to outside counsel on, but which you have to constantly pay attention. Everything from contracts that our facilities have with outside vendors, particularly of course, when they provide or call for the provision of medical services. All of those are constantly being reviewed from a compliance, regulatory perspective. Hiring decisions. Marketing decisions. What we want to offer to try to entice our numbers to go up. Things like that. On a day-in/day-out basis, the legal department, the compliance folks, are constantly being called in to weigh in on what's permissible and what's not.

I think as an outside counsel, sometimes you feel like those issues may not come up so frequently because you might get a call once in a while. We certainly reach out to outside counsel when necessary, but there's so much that goes on on a day-in/day-out basis, just as a matter of routine that, really, I don't know if it surprised me, but certainly, was surprising in how much of it there is.

Adams: We do a robust amount of health care work, but we get the issues presented to us generally on a sort of one-off basis, and we're not really weaving together the patchwork of legal, ethical, professional standards that come into the health care space, because this is a highly regulated profession. This is, not to be flippant, but would you agree with me that in the health care space, it's really a patchwork of all kinds of different laws and regulations?

Solano: Yeah, because look, you're dealing with providing medical care. At that point, you're dealing with not just the Anti-Kickback Statute, state Stark Law statutes or regulations, but you're also dealing with Board of Medical Examiners and their regulations, the standard of care and the Board of Nursing in our nursing facilities.

So, you have all of that. You have federal regulators who oversee the payment of government payors, like Medicare. You have state regulators involved in Medicaid payments. You have state insurance fraud prosecutors involved in the use or the filing of claims with the insurance companies.

You're right, it is a patchwork of both regulatory schemes at the federal level, at the state level, some of which deal with the payor part of it, some of which deal with the medical services part of it, the referral part.

The space that we're in, which is long-term care, includes both what we call skilled nursing facilities and assisted living facilities, which are assisted living for senior citizens. You start to impact, in our state for example, New Jersey Division of Consumer Affair Regulations. So, you really do touch upon so many different regulatory schemes that it is a comprehensive web of compliance requirements in a regulatory scheme.

Adams: I have once or maybe twice said that the idea of compliance issues arising in a heavily regulated profession such as yours is inevitable. I first want to shift into a discussion of compliance programs. How do you get a compliance program off the ground in a way that's defensible, if examined, but that is going to have the intended effect of ensuring your organization's compliance or at least most of the time?

Solano: I think through a lot of work is a short answer. To be honest, it takes a lot of work to get to that point. I was fortunate that obviously CareOne has had a long history, and so they've already had a compliance program in place. But I think that the question is no different in terms of continuing to ensure that your compliance program is adequate and robust enough to deal with the various issues that come up.

I think the answer is you step back, you look at the regulatory schemes that you have to comply with and you start to see where the services you provide, the arrangements that you have, will implicate those schemes. And you have to break it down by pieces, like I said before. For our Medicare payments and submission of claims, we put in all types of audit programs and things to make sure that our billing is appropriate, that we're not unintentionally filing a claim that can't be supported, that the documentation for it is there.

That falls in a varied compliance program, but you have to break it down that way. On the more sort of traditional compliance program that we often think about -- in terms of having a reporting structure, a hotline, an officer that answers questions -- you put in that program to the best practices. You seek advice from others in the industry on what they're doing. You're constantly reevaluating it.

I think it starts with having a strong compliance officer whose duties are to sit there and raise a red flag when appropriate to do so. We have that here. I think the two most important things about a compliance officer are, one, that they're very knowledgeable and unafraid to raise a concern or a red flag, but two, that they do it in a way that's not obstruction to the business, but actually trying to help the business grow and prosper in a way that's compliant with the law. That second part is as important as the first, because that second part is really what gets people to come to compliance, because compliance will help them stay on the right side of things, avoid pitfalls. If the officer is someone who's willing to work with the business to achieve what they want in the proper ways, then

the business folks aren't going to look to skirt around or avoid compliance. It doesn't become the black hole that you try to avoid. Instead, it becomes part of the process, the culture, of what you just need to do, and folks know that.

I've seen that firsthand here, that having a culture where people feel comfortable coming to their compliance program officer, because they're there to help and to help you avoid pitfalls, is a necessary part of the program.

The last thing, Matt, it's not just getting it off the ground, as I think you recognize. It's when you see those really big issues and, like you said, you or others at Fox Rothschild get a call. It's because something has gone bad. So the idea there always has to be, or the plan of action there always has to be, deal with the outside lawyers, fix the problem, try to get a handle on it and then go back and see, "Okay, where was the breakdown? Why didn't we catch this?"

I think any company, and I hope... When I was on your side of things, dealing with regulators and law enforcement or other entities, you hope that they understand that you could hope for the best and you try to put in as comprehensive a program as possible, but you're not always going to capture everything. And if you're doing it in good faith and you're doing it in a way that's intended to, what you hope to see is that when a problem does come up and you have to deal with an administrative action, or worse, that you are self-correcting, learning from that incident and trying to see if there's a way to avoid it going forward from repeating itself.

Adams: I want to revisit in a moment the sort of inevitability of these compliance issues. But I want to go a little bit more specifically into what you are seeing vis-à-vis government enforcement action, and see if it's consistent with the phenomenon that I see, which is one of an extensive amount of data-driven enforcement.

You mentioned more than once since we've started talking CMS, talking about Medicare, talking about Medicaid. I have just seen in my own practice, a tremendous amount of enforcement that is either unabashedly driven by data, where they're looking at certain providers where they fall on the norms, or and seeking to enforce on the outliers. Or other instances, where it's clear to me that maybe it used to be that the insider threat and whistleblowers was the predominant way that these enforcement activities began. It seems to me that there's a shift to data and that objective facts are almost being substituted by some level of speculation, just based on numbers.

Any comment on that? Anything that you've seen firsthand on the front lines with what I broadly refer to as data-driven enforcement? Because to me that's a scary proposition.

Solano: Look, I think the government -- from just interactions with them before I was here and since --proudly touts its data-driven, investigatory or review of claims being submitted to the government for payment. I agree with you that the concerns are real. I share the same concerns because the data may be a good starting point, but it's really hard to make any conclusions, or the regulators should not be making definitive conclusions, based only on the data. Because it doesn't tell the whole story.

There could be lots of reasonable explanations for why things are outliers, for why things look strange. That type of follow-up analysis on the data is required. Unfortunately, I've seen too many times when it's not necessarily employed. You might see some outlier in some space, and just hypothetically speaking, you might see some facility that's an outlier in the types of claims that it's filing that it hasn't done traditionally. What you can't have, and what you shouldn't have, is jump to a conclusion that something was done improperly. It's fair to raise a question about it, but I hope that

the regulators keep an open mind. Sometimes I'm afraid that they don't always do that. They see the data. They form their conclusions before actually digging in to see if there's an explanation for that.

I think, and I've seen this before on your side of the aisle, I think with COVID in particular that is something that's important to keep in mind. I say that because obviously the pandemic changed all our lives, but in the medical field, it meant that providers might be having to provide services in ways that they did not traditionally.

I think that includes everybody along the health care spectrum: individual providers, pharmacies, long-term care facilities like ours. I know, and I've heard tangentially of incidents, in which, for example the retail pharmacies were doing the COVID tests in the parking lots. Nobody knew how do you bill that, right? Is that an office visit? How do you bill the folks who got vaccines at a local CVS and we're doing it in the aisle of the store? Does it count as an office visit, is it not?

Those are the kind of things that you're going see what I would call "odd billing" numbers, and data that seems to be off that will set things in motion. Hopefully that will require some explanation, but I think regulators need to be mindful that particularly with the pandemic, which, unfortunately is maybe at a better place but not over, you will see some outlier and data information that may not tell the whole story.

Adams: I'm struck by that coming from your perspective obviously, because the COVID wrinkle on that was something that I wasn't exactly focusing on. I was thinking of a particular doctor that I was representing and he was examined for being an outlier as it related to a particular blood test.

He was a cancer doctor, and the government tried to challenge his reliance on this particular diagnostic test, and therefore his billing of that particular diagnostic test without the concept in mind that he was treating the sickest of the sick patients. People came to him literally when they wanted a few more weeks with their family. That was how dire these patients were.

I sat down ultimately with the government, and their medical expert had no experience in oncology. He was an emergency room doctor. And that was the government's expert trying to convince a world class cancer doctor who's literally saving people's lives, at least for a sufficient time to allow them to say goodbye to their family, that they were running a blood test that was medically unnecessary in his judgment. It really, to me, struck me as taking away medical judgment from providers.

Solano: Yeah I agree. Look, I think that's the risk, right? To what extent are you taking away medical judgment from the providers? Ultimately, they're the ones who have the expertise, the ability to make those kinds of calls.

You can't take that away from them, from regulation, but there is a fear that you will. What you have to hope for is that they have the right-- and by they, the regulators, whoever is looking into it -- get the right information on their side and are open minded enough to listen to the experts and to defer to that in the appropriate circumstances.

I had similar experiences. I represented a number of doctors and medical providers involved in tele medicine services, which the government often looks at with a jaundiced eye and would sometimes question the provision of those.

My argument was always, you don't regulate the practice of medicine, right? If the Board of Medical Examiners of the particular state decides that it's in their interest to allow that to happen, then you can't, through your overregulation, dictate what the practice of medicine is. You sometimes end up

doing that. If you start to question every bill provided by telemedicine doctor or look at it with a suspicious eye, you're gonna deter folks and chill them from wanting to provide those kinds of service.

Adams: To me, it's a striking contrast, right? Because you go in and try to convince the government that a doctor is not operating a pill mill, and they seem to recognize that there's medical judgment in prescribing certain drugs. But when it comes to the dollars and cents of billing a entitlements program, they seem to take a different approach. Right?

Solano: Yeah, yeah I think that's right. I think that they often take too hard of a line on what's appropriate to bill and what's not. Look ,and I don't mean to say that there's not, unfortunately, parties out there that do clearly violate the law, right? They bill, double bill for things, they bill for services that are provided, they bill at higher codes than they should. I'm sure that, no one can deny that there's a certain level of fraud in the industry. That's unfortunate, but that's not everyone, obviously. And sometimes the billing can be complicated and sometimes it's done for appropriately, right reasons. Sometimes it's done innocently wrong.

I think it's important that the regulators recognize that there are various explanations for things and why things might be happening.

Adams: Yeah, and to me that's the job of good lawyering is really to get in there and advocate.

I want to move to a different topic and make a hard pivot. We talked about the culture of compliance, and I think you properly couched compliance as really having two components: whether the compliance program is robust enough and then whether it's actually complied with, if I'm properly paraphrasing...

Solano: Yep.

Adams: ... your comments from earlier. How do you install or instill in an organization as large as yours a culture of compliance? Because your organization has a tremendous reputation for compliance, at the top of its field. But how does an organization, even coming on the heels of maybe a compliance issue, get buy in from its people that doing the right thing is the only way? Because it's apparent to me that your organization has done that. Where does that come from?

Solano: I think it has to clearly start with the top. I've heard this phrase often used by the government. They often talk about the negative culture at the top or bad culture at the top. And I think the opposite is also true. You have to get buy-in from the very top, right? Because that will stop anybody who does not want to follow through with their compliance or anybody that has objections from being able to go forward.

If you have buy-in from management at the very top, it makes the job of the compliance officers easier. Because when you say, "No, we cannot do this way," that there's not somebody higher up or a CEO or a president of the company that's gonna say, "Nope, we are gonna do it that way." Because that kind of undermining is toxic to a compliance program.

I think fortunately here we have that at the very top. Once you have that, then it's a question of training. You do the training online, you do the policies to folks, you explain it to them. But then, the everyday actual experience training in which people will come innocently and say, "I want to hire this." For us, for example we have all these facilities where we have residents that come in. We have

relationships with hospitals and different medical providers who know us, think highly of our level of care and refer their patients to us.

Obviously the patient has the ultimate choice. And someone might innocently come in and say, "Hey, can we set up this kind of financial arrangement with the fifth medical provider, because they've been referring work." It's not a fee for referral contract that would be illegal. It's a legitimate effort to try to enhance their relationship. You have a conversation with them and you explain to them what the problems are with doing any kind of arrangement, for example. It's that kind of teaching and learning through the everyday experience world that people start to become used to it.

Once they're told no several times and people just know. And I'd say that we get here at the legal department a number of questions asked, but a lot of other ones never come to us because the folks who run our facilities, the folks who are the ones in procurement and other places, just know what the answer's going be because of the fact that they've learned through the process of -- whether you want call it trial and error or just experience.

But I'll end where I started, which is, that only works if every time you say, "Nope, you can't do it this way, but here's how you can." That person doesn't have the ability to go above you and get a different answer and change that. So, you really have to have buy-in. I think it goes back to having to have buy-in from the folks at the very top of the organization who will back the calls when made.

That doesn't mean that there's not sometimes robust discussions. I think you get credibility and this is what I was talking about before. When the business folks come to you and say, "We want to do X," I think you get credibility and buy-in when you don't simply say, "No, you can't do that, too bad." But rather when you say to them, "Nope, you can't do it that way, but let me see if there's a way that we can accomplish your ultimate goal, if it's a legitimate one, in a different way. Let me see if I could talk to outside counsel and see what they think about this and see what their experience is, what others might be doing."

Sometimes the "no" becomes a "you can in this way, not in the way you were looking to do it." I think you need to be able to do that where appropriate, because that'll get, like I said, it'll get buy-in from your business folks that you're not a place where requests go to die, but rather a place that works with you and actually a partner.

What you always do with any client -- and we're a client to our business divisions -- you tell them about the risks of what would happen. In the health care space, unfortunately, there's more than enough examples of folks who have gone the wrong path, or things that the government has looked at and taken a position on that are catastrophic for companies. They're catastrophic for individuals who end up in jail or lose their livelihood. They're catastrophic for companies that pay huge fines. So, you say to them, look, I can't approve this because the risk of the government coming in here and frowning upon this stuff is going to result in dire consequences.

Usually when you explain to them in that way, it usually helps people see the benefits of making sure that you mitigate your risk and you comply with the law.

Adams: You and I have both been in the situation of advising a client that maybe doesn't have the best compliance program. We are strongly urging them to maybe install a compliance program that may be a bit more robust and may be a bit more complied with, as you put it earlier. Where I start when I do that is, I go right to the Principles of Federal Prosecution of Business Organizations found right in the Justice Manual. I say, "This is what federal prosecutors look to to determine whether they

are going to bring criminal charges against an organization, or they're going to give them the benefit of the doubt when inevitably that patchwork of regulation, something goes awry."

In that highly regulated environment -- and this just isn't health care. This is any highly regulated profession -- I sit down right with those principles and start working through them. I find that to be a compelling way to convince a client in that scenario that this is the right way. And there's really only one way to do this, and that's the right way. Do you get into the weeds in-house and as part of your efforts to instill this culture of compliance by actually sharing that sort of practical reality with your people?

Solano: Yeah, look, it depends on the circumstances. Obviously, at certain levels you don't. You simply say, "Look the consequences." It depends on what it is. If, in certain circumstances, where it's a clear answer, the answer is no and the law is clear, you say no. Where it's a question of evaluating the risks or the tolerance that the government might have for certain programs, you need to convince somebody. You might have a longer discussion with them. That includes things like, "Look, when the government looks at this, this is what they're doing."

Usually those conversations happen on a higher level where the company is trying to make a more strategic decision about, "Do we want to go in this direction? Do we want to enter this business line? Do we want to institute this new program?" You look at other examples of what the government's looking at and where they have concerns. In those conversations, you'll say, "Look, when the government looks at this, here's what factors they're going to analyze, and this is what you're risking," to use that as leverage, if you will to get buy in. Definitely, you do some of that.

Adams: We've spent a considerable time talking about how the benefits of a robust compliance program that's complied with by people and that includes instilling a culture of compliance. Let's now shift into sort of what happens when there is an inevitable compliance issue. What is the number one compliance issue that you're seeing in the health care space today?

Solano: I think where we see it, and it's a little bit different than other medical providers, but I think only in degree, I think everybody sees this is in the submission of claims to the government for payment. The compliant risks, there are a number up front, right? Is the service actually being provided? That's a low risk, but it's still something, obviously you want to make sure that the service is being provided. The second thing is, is it being properly documented? So, when we get audited, or if we get audited, can we substantiate that claim and that those services were actually provided?

The third level is, okay, services are provided. It's documented, are you billing at the right level? It sounds silly, but we actually, we have billing specialists who look to make sure is this being billed at the right rate at the right code.

And then when you submit all that, obviously there are some times where in the Medicare world and in the provision of services world, you are not always recovering what you're supposed to. There's co-insurance, there's deductible payments. Sometimes you don't recover that because a person can't pay it.

Then there's that sort of fourth part: Are you making your efforts to recuperate that money or writing it off as bad debt? There's all these requirements in the law that you have to make reasonable efforts to recoup the money before you can write it off.

So, that's the biggest risk, I think. The reason I say that, Matt, is because it goes back to where you had said it earlier: That's the easiest place for the data mining to occur. You look for certain billing

codes. You see all of a sudden that this one facility or provider billed in the range of $150,000 a month at this one code and then all of a sudden you see a spike in month five that goes on for several months and then it drops. That will cause a red flag. So from a compliance perspective, because that is where the regulators are focusing in, that's where we always want to make sure that we're doing the right thing.

You mitigate against that by a number of steps, not just your compliance program. We do our own audits. We will, from time to time, audit certain files to make sure that the billing is being done properly.

So the first part of the risk is the data mining that they identify you. The second part is when the CMS comes in here and does an audit. I t is disruptive. It is costly, it's disruptive, and the worst potential part is oftentimes they try to use extrapolation, right? So they look at a hundred claims. They find that five of the claims were improperly submitted because there's not enough documentation. Then they try to say, "Okay, for the last year, you have to pay us back 5% of the total amount paid on your claims." Even though that may not be representative.

When you talk about the nightmare scenarios, those are the biggest risks that I worry about when I think about the billing aspect of it, the potential for CMS auditors to come in. And to be blunt, that the reality is that CMS doesn't even do the audits themselves. They contract out to private third-parties who get paid based on a percentage of what they're able to recoup. So there is a strong financial incentive for the auditors to find payments that should be paid back because they're getting a direct financial benefit from that.

Adams: Dare I say, a perverse incentive.

Solano: Yeah.

Adams: If we start with the proposition, Ricardo, that in any highly regulated profession, it is inevitable that compliance issues will befall an organization. What in your opinion is the right way to handle that compliance issue once it pops up?

Solano: The right way to handle it is, once it pops up you address it directly, head on. You cannot ignore it, obviously.

Adams: Self-disclosure.

Solano: Yep. It depends on what it is and how serious it is of an issue. Do you go to the authorities and self disclose? There are certain levels to that. Sometimes from our perspective -- sticking on the billing example -- you might simply make a repayment and try and hope that that addresses the issue. If it's something more serious, you make the repayment and then you self disclose to local authorities and explain the situation.

I think you want to be a good corporate citizen and so you always balance the risk of self-disclosing. Are you buying a bigger headache when it's really a small one? Versus, this is something that we really wanna show that we caught it. We're going to address it, and we've taken these steps to resolve it. The third part is really the key part. If you're going to self disclose, you better be sure that you've done a good job of addressing it. Then the government, I think, is always going to look to see, "Okay, how do you prevent it next time? Or, how can you assure us that this is not something that's gonna continue to repeat itself?"

Adams: You mentioned a little while ago, I think, that one of the most significant threats to a health care organization like yours and what keeps you up at night is the idea of billing audits. Is that correct?

Solano: Yeah. That's one of the areas for sure.

Adams: Let's say that's the central focus today of your anxieties as an chief legal officer of a major health care organization like yours. Where do you see that heading in five years? Do you see that only growing, or do you see that shifting in some other direction as the winds blow?

Solano: Sadly, I don't see it shifting away from that. Obviously there's other priorities that may come in, but I think that's always going to be a focus, right? Because it's where the money is. It's following the money. It's the money that's being paid out by the government and following it to make sure that it's being appropriately paid out.

Like I said, I don't think that the government is wrong trying to make sure that the billing that's being done of its health care programs is appropriate and warranted. I just hope that there's a balance there between making sure that folks aren't taking advantage of our medical payor programs, but also that you're not overly punishing folks for what might be innocent mistakes. What might not be mistakes at all, but what might at first point appear as a mistake. But I think certainly that is one area that I don't expect it to go away.

I will say this, just to go back, Matt, for a moment. I think billing is certainly a big part of it because so much in any health care space of what you're doing is billing under government payors.

But you know, an equally disturbing thing that keeps you up at night: whistleblower claims. The fact that so much of the litigation that you see oftentimes in the health care space and in our space involves individuals who claim that they identified a violation of law or public policy of someone, and then were retaliated against. That certainly always keeps me up at night as well.

Adams: Yeah, the insider threat. I think I'm quoted somewhere in a book about the insider threat being the most significant threat that exists to an organization.

I've got one final area that I want to delve in while we have a little bit more time remaining, Ricardo, today. That is technology. We have seen with COVID that there has been this complete paradigm shift into even more enhanced telemedicine than perhaps ever before.

You and I both know that telemedicine is one of the central focuses of the Department of Justice in terms of fraud and abuse. From the organizational perspective, how does an organization as large as yours keep up with the rapidly evolving technology, the increasing proliferation of telemedicine, and still remain compliant?

Solano: I think the answer is, unfortunately, you move slowly and carefully. COVID, you're right, forced us into areas to move a lot faster. But I do think that you need to move carefully because of the risks.

What I would say about the technology and telemedicine is, as things get more technologically advanced, the bigger for others to exploit it for improper purposes. That just means that the government's going to put a microscope on it.

When that happens, you want to make sure that as you're moving forward, that you're doing everything right, and that you're not doing something that the government is gonna now come looking at you down the road. So, you weigh the risks of, "Okay, if I allow for this enhanced and better technology to come into my system, what are the risks associated with it? How can I guard against it? If I move to a model where instead of live physicians on the weekends, I have doctors who can provide video conferencing services and provide medical services that way."

There's certainly a benefit to that, right? You might be able to save money. You might be able to provide for the patient better and quicker access to a doctor than you will if you had to have a live doctor there. You might be able to provide more specialized care from a physician, rather than having one attendant physician who specializes in one area, maybe a couple areas. You could literally have an open menu of numerous specialties all accessible through video conferencing or some type of telemedicine services.

I think that's something that is beneficial to patients and you want to provide to them. I think the way you try to guard against that is working with reputable vendors. That's number one. Know who you're dealing with. Doing your due diligence on it.

And then some of it's gonna be a little trial and error as new technology comes into place and you start to embrace it. What is the best technology? What is the right one? Where do you make shifts? What reviews do you need in approval to implement it? Things like that. What kind of audits are you gonna do? You try to look into those areas to see what helps.

Adams: Ricardo, I think you and I could spend the whole day chatting, but we're out of time.

I can't thank you enough for joining us on "The Presumption of Innocence." Thank you all to the listeners and we'll see you next time.

Solano: Absolutely. Thank you, Matt. It's been a pleasure speaking to you this afternoon.