***Regulatory Oversight Podcast*: Enhancing Compliance: The Power of Independent Monitorships in Consumer Protection**
Host: Ashley Taylor
Guests: Vincent DiCianni and Kevin Lownds
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Ashley Taylor:

Welcome to another episode of *Regulatory Oversight*, a podcast that focuses on providing expert perspective on trends that drive regulatory enforcement activity. I'm Ashley Taylor, one of the hosts of the podcast and the co-leader of our firm's State Attorneys General Team. And a member of our Regulatory, Investigation, Strategy and Enforcement Practice. This podcast features insights from members of our practice group, including its nationally ranked state attorney's general practice. As well as guest commentary from business leaders, regulatory experts, and current and former government officials. We cover a wide range of topics affecting businesses operating in highly regulated areas.

Before we get started today, I wanted to remind all of our listeners to visit and subscribe to our blog at RegulatoryOversight.com so you can stay up-to-date on developments and changes in the regulatory landscape. Today, I'm thrilled to share with you that I'm joined by Vincent DiCianni of Affiliated Monitors, and Kevin Lownds from the Massachusetts Attorney General Office to discuss the value of monitorships, their application by federal and state agencies, particularly in consumer protection cases. And how companies can use monitors to improve compliance, rehabilitate companies, and ensure better service quality.

Vin is the founder of Affiliated Monitors Incorporated and has led the company since 2004's president providing independent monitoring and compliance consulting services to various government agencies and regulated entities. Under his leadership, Affiliated Monitors has handled over 900 monitoring matters collaborating with numerous federal agencies and Attorneys General Offices on diverse issues, such as healthcare licensure and consumer protection.

Kevin has been with the Massachusetts Attorney General's Office for over seven years and currently serves as Deputy Chief of the Medicaid Fraud Division. During his tenure, Kevin has led several of the office's largest investigations and litigation, including the first indictments related to Covid-19 outbreak at long-term care facilities and the largest national settlement involving private equity liability under the False Claims Act.

Vin and Kevin, I want to thank you both for joining me today. Let's start off by level setting for our audience. What is an independent monitor? And when is it used?

Vin DiCianni:

All right. This is Vin. And I'll start off. Independent monitoring is really an alternative sanction that is used by a variety of government agencies. And what it is, it's sort of an enforcement tool that requires some oversight by a third party to oversee the implementation of corrective action, or changes, or things that an entity is not supposed to be doing. So the third party is a neutral.

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Usually, it has some professional responsibilities and requirements which go to the selection process, which perhaps we'll get into later. And they follow the mandates of the terms of it could be a settlement agreement, it could be a plea agreement, a deferred prosecution agreement, corporate integrity agreement, even an administrative agreement.

Sort of the mandate for the monitor is set by the arrangements that the government has with the entity that has to be monitored. That's a little bit of an oversight. And it gets used as we'll talk about in a great variety of settings, including consumer protection and in Medicaid and Medicare fraud matters, which, Kevin, I'm sure will address.

Kevin Lownds:

This is Kevin. In sort of talking through when this type of monitoring is used by state AG's, I think it's important to think about the way Attorneys General's offices have generally thought about the purposes of an enforcement action. When we think about what sort of bringing an enforcement action forward, we tend to look both backwards and forward. Looking backward is the traditional focus. What kind of conduct occurred? What kind of fraud resulted? What is the appropriate restitution or recompense for that?

And, typically, what we're looking at in the backwards-looking resolution is financial. Right? It's a monetary recovery. It's a penalty. It's restitution to the government agency that we contend was defrauded. It's sort of compensation for past misconduct. But I think many AG's offices, and particularly the mass AG's office, are also very concerned with sort of forward-looking resolution.

And as part of any resolution that the Medicaid fraud division does, we look not just at what's being done in the past to make up for what we contend was the problem. But what is the company going to look like after this resolution? And for some providers, that's easy. If you've got a kickback case and you contend that they were paying a kickback and they've agreed to stop paying a kickback, well, that sort of addresses the forward-looking problem.

But, oftentimes, the forward-looking question is more complicated. If a company is in a nascent industry and really struggle to understand what the regulatory landscape looks like, or if the company has had a variety of misconduct, the AGO may be interested in having checks in place to ensure that the company becomes compliant moving forward.

And for us, that's where a monitor comes in. They serve as a check to make sure that whatever we believe about the company's future conduct, what we need to see in order to be assured that our resolution is appropriate, that someone is in there to either assist in putting that program together, or ensure that we're getting the benefit of the bargain that the company has actually done what it has promised to do. And that's why the AGO I think has started to push for these types of resolutions more frequently.

Ashley Taylor:

Vin, Kevin has really given us a great sense of how a state AG's office may think about a monitor. Is there a different analysis that you find occurs in the context of a federal investigation?

Vin DiCianni:

Sure. If we're talking about healthcare fraud, false claims, and/or stock violations, or other kinds of things that the OIG for HHS would be looking at, there is a difference. And I'm sure Kevin can talk about this as well. But, typically, the OIG uses monitors in a variety of settings. Oftentimes, it is looking at the billing and coding submissions by a company and testing those. A random sampling over a period of time gets looked at. Sometimes they are looking at arrangement reviews and whether or not there's anything inappropriate about those types of arrangements. Sometimes they go into quality of care. Not that frequently. But they do. That's the federal side of things in the healthcare world.

The Mass AG's office – and, Kevin, you will please jump in. But the Mass AG's office, as Kevin has described, uses monitors in a much broader fashion. And in certain instances, in a way that is sort of a mentoring to help a company implement a compliance program or to test the compliance program to see if it's effective. And then perhaps make recommendations for improvement and those kinds of things.

In terms of the AG's offices that we have worked with, they often times can use a lot of different – I'll call it tools of monitoring to make sure that the company is doing what they're supposed to be doing under state regulations, federal regulations, best practices, billing and coding, all of those kinds of things. But, Kevin, please jump in and talk about sort of the difference that you see from your vantage point.

Kevin Lownds:

Yeah. The way I would describe this is I think there are two principal distinctions in the way that the federal government versus state AG's rely on monitors. And the first, which Vin just touched on, is in sort of the scope of the monitorship itself. And I think some of the scope differences – and I agree with Vin that I think we often tend to establish broader monitorships where the monitor may serve a sort of establishment role. Where they are working to establish a compliance program at a provider rather than sort of oversee an existing program. Those scope issues often relate to some differences in the types of investigations that state AG's versus the federal government may be pursuing.

I'll note that in the healthcare space, a lot of federal investigations often deal with companies that are large sort of pharmaceutical companies or large hospitals. And in those contexts, those companies often have pretty sophisticated compliance programs to begin with. They have compliance departments. They have compliance officials. They have a very sophisticated general council's office.

And so, it is often less the case that those companies require really mentorship from a monitor in establishing that program. And the goal is more to establish a check on that program. A lot of investigations that state AG's may deal with may involve companies that have far less sophisticated internal controls. And when a company has sort of propped up six, seven years ago, they are former sort of clinicians who have formed their own business or things like that. We see that a lot in the home health space in Massachusetts. We see that a lot in the autism services space. Those providers may have very little experience with compliance and very little experience with regulatory sort of issues.

And as a result, when we're crafting a monitorship, it's not just that we want the monitor to check those companies and make sure that the audits are compliant. It's that we want the monitor to come in and really help those companies establish a compliance culture and a compliance program. And in that case, the sort of scope that we negotiate in the course of our monitorship is often wrong.

The other piece that I would note about the difference between the federal and state approaches here is that the negotiation is a bit different for defense council with a state AG's office than it would be with the federal government. At least in the healthcare space. In the health care space, DOJ, or the US attorney's office that is handling the case typically negotiates the backward-looking resolution that I described. The restitution payment. The financial penalty. Whatever. That is handled by the DOJ or US attorney's office.

But as Vin been alluded to, HHS OIG is typically the entity that negotiates a compliance program. And they often do it after a handshake has been reached on the financial piece. If you're defense council, you're sort of negotiating a financial restitution first. You reach a handshake with DOJ. And then you have to go into this HHS OIG process and negotiate either a CIA or some sort of modified CIA and see what happens there.

In the state AG process, these are all tied together. A negotiation over the scope of financial restitution is occurring at the same time as a negotiation over compliance monitoring or the level of forward-looking resolution that we would seek in our case. And as a result, I think for practitioners, it can be really useful to understand that distinction. I think companies can tend to be reluctant to sort of agree to monitoring. And I can understand why that would be the case.

But I would know from the government's perspective that early sort of commitments to compliance in a negotiation where compliance and financial restitution are tied together can be very beneficial to those companies because it may suggest to the government that this company is, willing to play ball willing to try to improve the issues that we talked about. An early commitment on monitoring can often result in a lower ultimate penalty that the government seeks because we understand that our forward-looking resolution has really gotten to the place we want to. I think it's useful for folks to understand that piece as they sort of figure out and navigate the state AG's landscape.

Ashley Taylor:

Kevin, as you were describing the differences, it brought to mind a number of conversations I have had with clients trying to describe the monitorship as a tool that is not necessarily inherently harmful or punitive, but a tool that can be used to either resolve a case or move a negotiation forward.

Vin, would you comment on that? You have experience in an AG's office and you have experience serving as a monitor as monitorships have proliferated around the country. How can we as defense council better explain the use of monitoring as a tool that can be effective rather than it being something that's necessarily a punitive aspect of the negotiation offered by the government? What type of language can we use as defense council to better explain that dynamic?

Vin DiCianni:

Oftentimes, when you're negotiating with the government, there's not a lot that you can offer. I mean, you can defend the facts. But when you're trying to get to a settlement, oftentimes it came down to just a dollar amount. And that's why monitoring is looked more as a probationary type of sanction.

And so, from the defense vantage point – and this is why I have been such an advocate for it. And I've talked to hundreds of defense attorneys around the country. Oftentimes, we hear from defense council or companies that were beginning a monitorship that their concern is that the monitor is really just an investigator. And that the case hasn't really resolved. And that the government eyes are going to be all over them for an extended period of time. That's not the case.

A good monitor is really looking to help the company improve and make the monitorship successful and bring value to the company by helping and pointing out those areas where the company may be deficient. When you're before a government agency – and, Ashley, you know this better than all of us. When you're before a government agency and they have pointed out some deficiencies in your client's practices, fixing those and doing it through the eyes of an independent to validate that those fixes are real, and effective, and can be maintained after the monitorship is a really important thing. That's one of the roles that a monitor can play. And a lot of times, companies don't realize that benefit.

The other thing that I think really needs to be thought about in terms of a monitor is that the monitor oftentimes is the bridge between the government agency and the client. If I'm talking to the government as the monitor and they're saying, "Focus on this. Let's look at this and see how they're doing." And I can tell the company it's going to be in the mandate. So, it's going to be in the settlement agreement. But we can give some direction to the company. It's really important for the company to hear that.

It's also important for the government to hear what the company is doing to fix those things. And that the efforts that they're making are legitimate. I'm really just touching on one aspect here of the benefits. I mean, there's many others. But I think that that's an important one. One, the value in terms of fixing things. And then the second, as I'm mentioning, is really being the bridge. Because the monitor is only going to be there for a certain period of time. It could be three years. It could be 5 years. And then we're gone. And you want to have sort of reestablished a good sort of – I'll call it working relationship with the government where they're not in your back. That you're not on their radar screen. And that you as a company can move forward with these changes that are effective to reduce the risk of getting in trouble again. I think those are some of the benefits, Ashley.

Ashley Taylor:

Kevin I was listening to the benefits as outlined by Vin and it brought to mind one question. You have seven years of experience, plus, in the Massachusetts AG's office. But you also have a significant amount of experience working with AG offices from other states. Can you talk about how this monitorship movement or use of a monitor as a tool and being used by other states, just talk to us about your experience in working with other states and how other states may value this.

Kevin Lownds:

Absolutely. Ashley, I think describing it as a movement is a good way to describe it actually, is I think we are seeing an increase across state AG's in trying to understand how to approach forward-looking resolution in addition to backward-looking resolution. I think there's a couple pieces to this. I think one is that, for a long time in healthcare fraud in particular, the federal government took a leadership role in a lot of different cases.

And I think over the course of the last 10, 15 years, you have seen an increased independence in state AG's in bringing their own healthcare fraud actions. And so, in those previous – in times when the US attorney's officer or DOJ was taking the lead on cases, you saw oftentimes they were relying on HHS OIG to enter into a CIA or a compliance program. And the state AG's office would sort of go along but was not necessarily negotiating this themselves.

I think what you see today with state AG's exercising a lot of independence in the area of healthcare fraud prosecutions, especially in the civil area, you are seeing state AG's start to grapple with the question of, "Okay, I've resolved this case civil. What am I going to do with this provider going forward?"

And I think, generally, when I was listening to Vin, I was thinking of the fact that, when we do a settlement agreement, we sign the agreements, but so does the health and human services agency that oversees Mass health in the state of Massachusetts. And I think about the case as where there's a potentially suspect provider that was brought to our attention by the Medicaid agency, for example.

When we bring that provider back to the Medicaid agency and say, "We are not going criminal. We are not trying to put this provider out of business. We are proposing a civil resolution for you to approve and for us to approve," it makes it a much more palatable proposal when there is a compliance commitment in that realm.

And so, I think a lot of state AG's around the country are seeing that, as they try to figure out what to do with cases that may not fit into a criminal bucket, but, also, there is something that needs to be addressed, some penalty that needs to be applied, monitoring is a way for the states to continue to work with their Medicaid agencies and other state stakeholders in the non-healthcare fraud context to sort of assure state actors that this company is worth keeping in business. And so, that's I think an important thing that states are grappling with as they sort of navigate these relationships because there tends to be more of a separation between the feds and state Medicaid agencies. The Medicaid prod control units work hand in glove with those agencies. When they're navigating this, the compliance monitoring is a really important piece.

The other piece that I would note, Ashley, is that state AG's are spending a lot of time in the nursing home space. You're starting to see resolutions come out of states like California, like New York, like Massachusetts where nursing home, large nursing home chains are facing civil liability. And, typically, these cases involve quality of care concerns principally. Quality of care. Understaffing. Lack of staff training. Things like that.

When you're talking about quality of care, the forward-looking resolution is the most important. The first thing on our minds is how do we best improve the quality delivered at these nursing homes as soon as possible? You saw in New York a series of lawsuits filed over the last year to

against nursing home operators. And they sought immediate injunctive release. And what did they seek? They saw compliance monitoring as part of that immediate injunctive relief. I think you're going to see more of that in Massachusetts.

We recently reached a resolution with a large operator of 17 nursing homes here, we agreed to 4 million in penalties, which is a significant number but is not among the largest financial settlements that we've ever reached in the Massachusetts AG's office. But it includes the largest compliance monitoring program we've ever done. It includes compliance monitoring at 10 nursing homes across the state. And a very significant sort of – the monitor will have a very significant role in those nursing homes. And you can see that that's the focus of the investigation. How do we improve quality of care going forward?

I think as you see these two trends, one, a focus on quality of care, particularly in long-term care. And, two, independence of state AG's increasing, decoupling from federal investigations, you're very likely to see an uptick in monitoring because it implicates both of those concerns.

Ashley Taylor:

Kevin that development of states exercising their independence rather than simply going along with a federal investigation is something we see not only in the healthcare context, but in significant consumer protection matters and in antitrust matters. I think it's something for practitioners to understand and explain to their clients how the AG's offices nationally have evolved in this regard. And that level of independence is something that I think would be helpful for everyone to understand at the beginning of a case. How is an AG's office postured? What is their primary goal?

And I'm also thinking of my experience in the Virginia AG's office some 20 years ago where we had a quality of care issue. And I remember reading the newspaper articles about the case and how we were focused on the patients and transfer trauma. It's not as easy as shutting down a home. You still have patients who need constant care.

And I remember thinking, if you read the press, you see enforcement. But in the AG's office, you have to be concerned holistically about the patients and where they go. I think the monitorship is an aspect that can be thought of as a positive sword for a defense attorney to put on the table in many cases affirmatively as part of a solution rather than always viewing it as a negative development.

Vin, would you talk about how you as a monitor could help frame that issue so it's viewed in a more positive light?

Vin DiCianni:

Sure. And you raised such a good issue there, Ashley. And Kevin mentioned it early on in the points he was making. And that is defense attorneys thinking about when they're negotiating with a government agency. And it could be Medicaid. It could be consumer. It could be antitrust. It could be the whole variety of acronyms of agencies thinking about going in and proposing changes through a monitor as a way of resolving a matter. And doing it early. Because I think you do – and, Kevin, you can address this again. Thinking that you might get a better ear from

the government if you sort of acknowledged, "Look, we had a problem and we're fixing it." Or we have fixed it. And we fixed it through the eyes of an independent.

There's some significant consideration that I think you receive from the government, when you move forward as a sword, you have to at some point be realistic. And the three of us on this podcast all have deep experience in getting to the point that you have to try a case or cases that should be resolved prior to going to trial. And the cases that go to trial, they have to because of some variety of reasons.

But there's a lot of cases that can be resolved in a way that gives the government what it's looking for. As Kevin is saying, it's going to want some kind of payment fines, penalties, what have you, or reimbursement, restitution. But it's also going to be behavior change. They're going to want to have some sense that the behavior that got the company before them has been addressed. And you're not just sweeping it under the rug and moving forward with the same old approaches to fixes.

The AG's offices and all these government agencies that we're monitoring for are looking for realistic fixes. And that's where I believe defense council can play a very significant role. And I've worked with your office, as you know. And I've worked with many officers around the country, and companies and entities around the country where they embrace the monitor. And they said, "Look, we understand we had some problems. We're looking to fix those." And sometimes it's hard for them to fix themselves.

I think as you're talking – and, Kevin, please weigh-in on the value proposition for government agencies when attorneys come forward and say, "We would like to resolve this matter." Because I do think it's an important point, Ashley.

Kevin Lownds:

Yeah. I do too. And I think starting with the principle, our position is that monitoring works. And we have empirical evidence of that. We have had situations where we have agreed to what we sort of describe – we tend to think of sort of different types of compliance resolutions. We consider external compliance to be one with a monitor. We also often agree to resolutions involving internal compliance where the company agrees to certain steps that it will fix.

Where we've agreed to external compliance or situations where a monitor is actually involved in fixing the issue, we have seen actual data that suggests that the providers have had better surveys. We have had providers in monitorship come off CMS's special focus facilities list. We have seen their recertification scores go way up under monitoring. We have not seen the same types of results, internal compliance situations, at the same level that we have with external monitoring.

Our view is that that is the most robust sort of approach to trying to fix the issue. And it has been the most successful in the past. How do we react when a solution that we believe to be effective is presented to us early in a negotiation? We react very positive. It shows, one, the company's commitment to trying to actually correct the issues. And, two, it leads us to believe that we are on a path to potential resolution.

It has been my experience that it is actually much harder to negotiate a robust monitoring program with someone who is unwilling to do it that it is to negotiate a financial resolution with someone who is reluctant to pay up. And I think the reason is money is money. At some point, you're just talking turkey on it. And you may end up in a situation where folks have different leverage and the government sort of makes its move and threatens a lawsuit, or is ready to file, or things like that. And then, suddenly, things change. It's not that challenging to end up negotiating dollars, I don't think, in the end.

Monitoring with a company that is unwilling to do so is actually a real challenge. And if a company is unwilling to play ball on robust compliance, those are the things that have led us much, much closer to the brink of litigation than a sort of financial resolution that can't be done.

And so, my take is always, if we have an agreement on what the forward-looking resolution looks like, we're on a much smoother path than if we're going to get caught up in the muck on compliance monitoring. And as you can imagine, our office tends to view a reluctance to let the monitor see books and records. A reluctance to let the monitor see financials. A reluctance to let the monitor conduct audits of quality of care or things like that.

We tend to view that very skeptically because our question is why. What is it that you're trying to hide? If you don't want to pay us $2 million, we know why. We understand why you wouldn't want to give us money. That makes sense. It's a little bit more suspect to have a reluctance to agree to this type of thing. I understand cost is a factor. That is what we often hear. But it tends to be a tougher road when there is genuine conflict over that issue. And I think companies do much better in negotiations with us when the monitoring process and sort of agreeing on that is smoother.

Ashley Taylor:

Kevin, those are very helpful and practical insights into how your office and state AG's view the monitorship issue. Vin, I know you will agree with Kevin that monitoring can work. What other messages would you want to leave our audience regarding monitoring? We always want to leave with practical tips.

Vin DiCianni:

Sure. Probably a couple. One would be that it does work. And when you get a good monitor that understands the role of the monitor and has experience as the monitor, there's efficiencies that are created by that. And so, the monitor doesn't have to figure out what to do and start from square one.

The other thing that comes with that is benchmarking. Because of the vast experience that we have in a variety of monitorships in both the Medicaid, consumer protection, antitrust, you see what other companies are doing. And you can say this is a really good thing that you're doing. And bring that message back to the AG's office.

At the same time, it gives the company an opportunity to not only fix things, but really to tell the staff and give the staff the freedom to speak up and say, "Look, we recognize that we had problems. Here's some ideas on how we think these things can be fixed." That's the behavior change piece, Kevin, that I think is really important. It is dollars and it is compliance. But at the

end of the day, a good compliance program and even a monitorship really can help the company change its ethical culture to be one of compliance, to be a speak-up culture, and to do the kinds of things that compliance professionals are looking for.

One other point, Kevin, if I can. And that is to talk a little bit about private equity. Because it has gotten involved, as know and as Kevin knows, in the ownership and the acquisition, a variety of different healthcare businesses, corporate companies, and government contractors, and that kind of thing. And we've worked with a number of them who have agreed to a monitorship because they recognize that the value of their ownership interest is improved by an improved company.

Rather than sweeping things under the rug and sort of turning their back on effective changes, they're embracing it. And I'll tell you, some of the most successful monitorships we've had, and we've worked with Kevin on a couple of them, have situations where the private equity owner has come in and invested in compliance and invested in the types of changes that have improved the company's business and business operations. Those are the messages that I wanted to leave. And, again, I think they're valuable.

Ashley Taylor:

Well, Vin and Kevin, I want to thank you both for joining me today. And this has been a great conversation. And I'm sure our listeners found great value in your insightful perspectives. Thank you to our audience for tuning in. And remember to subscribe to this podcast via Apple Podcast, Google Play, Stitcher, or whatever platform you use. And we look forward to you all joining us next time. Thank you, Vin. And thank you, Kevin.