



DOJ's New Guidance on Evaluating Compliance Programs: What You Need to Know

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Jose Garriga:

Hello, and welcome to *OnAir with Akin Gump*. I'm your host, Jose Garriga.

The Department of Justice recently issued guidance and made statements in support of effective corporate compliance programs. On today's program, we'll be examining that guidance and looking at questions such as, how does the DOJ incentivize the development of strong compliance programs? What sort of credit does a company receive for its compliance program when facing a False Claims Act allegation? How should a DOJ criminal prosecutor evaluate whether a compliance program is well designed, well functioning, and well applied?

My guests today are Taylor Jones and Matt Wetzel, both senior counsel in Akin Gump's health care and life sciences practice. They provide health care fraud & abuse and compliance guidance to life sciences companies.

Welcome to the podcast.

Taylor, Matt, thank you both for appearing on the show today. This compliance evaluation guidance is critical for companies in the health care space, so, let's start off with a little background.

Taylor, could you please tell me about the DOJ guidance? What does it mean, and whom does it impact?

Taylor Jones:

Sure. As you stated, DOJ released this guidance fairly recently. It came out at the end of April. The purpose of the guidance is to provide details for white-collar prosecutors on how to evaluate the effectiveness and adequacy of compliance programs in the context of these DOJ investigations and cases. The new guidance does a lot of things, but, mainly, it reorganizes existing guidance, and it adds details to and clarifies the existing guidance and addresses some questions that folks in the industry have had since the original guidance, which was released in February of 2017, came out. We believe that the purpose of this guidance was really to harmonize and consolidate the guidance with other existing guidance and department standards and to provide a new context through which these DOJ prosecutors can better evaluate compliance programs.

Jose Garriga:

Thank you, Taylor. Matt, looking at this DOJ compliance evaluation guidance, what are your top three takeaways or impressions?

Matt Wetzel:

Sure. Thanks so much, and thanks for having us here today. This guidance the DOJ released in April is fairly lengthy. It's about 20 pages or so with a lot of information. It's a lot of text, so culling through it can really prove to be a time-consuming task. I'd say as far as the three top takeaways, from my perspective, first, this seems to be yet another statement or continuing series of statements from DOJ in support of private-sector compliance and the need to partner between the government and private entities for rooting out and preventing fraud and abuse. You can see this in the practicality and pragmatism that DOJ takes in the guidance document here.

First, it talks about there being no one roadmap to compliance, the scalability of compliance. These are concepts that are long embedded in the work that the government has done in evaluating compliance programs. Guidance takes care to note that the degree and scope of a compliance program can vary based on the industry, the industry sector, based on risk aversion that a company might have, the geographic and market distinctions that a company might be facing. I think that's important to take note because, as the DOJ comes in to evaluate a compliance program, to evaluate how a company is doing in terms of preventing fraud and in the case of health care fraud and abuse, it's important that DOJ looks at that program in context and not just in a vacuum.

The DOJ talks about compliance as an ongoing and evolving process, about measuring compliance from the time of the bad acts to the time when the charge is issued, and how has this program evolved and developed and changed over that time. And it also looks at whether a company has appropriately allocated its resources based on that risk. For example, is a company overemphasizing minor risk or lower-risk issues, for example, hospitality versus higher-risk issues, for example, interacting with third-party distributors and sales intermediaries?

I would also say a second top takeaway would be the fact that the guidance looks at learning from behavior. It's not just does the company have the right communications? Does it have the right training? It's looking at whether senior and middle management have modeled the right behavior in both their words and their actions, so digging deeper. Not just saying, "Did you have a communication check?" but rather, "Did you have a communication? How did you get that out there? Did the senior management model that behavior that they alleged to support in that communication?"

They also look at whether there are specific examples of past bad acts that are used in training programs. It's not just training on what the policy says, but this is what the policy says, and this is how it's been violated before, and this is why that was a problem, so really giving the employee base that solid understanding: what does it mean to follow the actual compliance policy, not just the policy itself?

Third, I would say the way that the Department of Justice defines "effectiveness." It's not looking just at whether a company has a program that's based on the so-called seven elements of an effective compliance program, although, over the past 10 years, we've heard that as the 10 elements, the 11 elements. There's this sort of amorphous concept of an effective compliance program. The DOJ asks, "Is the program applied earnestly and in good faith?"

In other words, what's the intent of the compliance program? Is the intent to serve as a fig leaf? Or is this supposed to be meaningful compliance, the difference between a check-the-box program—something that's on paper that might be implemented sporadically or not consistently across the company—versus a meaningful compliance program that looks at whether the employees are actually accessing the information and absorbing it. As I mentioned before, are senior leaders modeling the right behavior? Are you taking the right degree of risk into account when allocating resources?

Those are the types of, I would say, takeaways: the pragmatism, the focus on effectiveness, and the emphasis on learning from behavior. To me, those were three things that stood out substantially from the guidance.

Jose Garriga:

A reminder, listeners, that we're here today with Taylor Jones and Matt Wetzel, senior counsel in Akin Gump's health care and life sciences practice, discussing the Justice Department's new compliance evaluation guidelines.

Taylor, we've listened to this very thorough exposition on Matt's part. How do you, then, advise clients or other companies to use this compliance evaluation guidance? And is it, in fact, required reading for all in-house counsel and compliance officers? If so, what's the most important part?

Taylor Jones:

I would say it is required reading, just to get that out of the way first. I think this is very, very useful for in-house counsel and for companies in determining the adequacy of their compliance programs. I mean, obviously, this guidance is meant to provide guidance to prosecutors in the context of a DOJ investigation when determining whether or not criminal charges, fines or monitorships are warranted.

But, that said, I think this is extremely useful outside of the context of a DOJ investigation. Obviously, you don't want to wait until the DOJ is knocking on your door to then examine whether or not your compliance program is going to pass muster. I think every company in this industry needs to review this guidance and assess their individual compliance programs based on this guidance, because I do think it provides a lot of useful detail in terms of how DOJ is going to review the various elements of your compliance program as well as the process through which you developed your compliance program.

In terms of my opinion of what the most important part of this guidance is, I'd probably point to two different elements. First, I think it's very interesting that DOJ has put such focus on the need for an adequate risk assessment on behalf of the companies. They note that a risk assessment is really the starting point for determining whether or not your compliance program is well designed. They want to look to see that you have identified, assessed and defined your risk profile, and they want to see how you have devoted adequate or appropriate scrutiny and resources to the various spectrum of risks that your company might face.

The second item or second element that I think is also very important to take note of is this idea of the need for continuous improvement as it relates to your compliance program. As Matt noted, the DOJ has placed a lot of emphasis on learning from your past experiences and your past challenges with respect to compliance, and I think that that's an interesting concept that we've not necessarily heard from DOJ before. They really want for your compliance program to be evolving. They don't want you to implement a compliance program in year one and then have that exact same compliance program in place in year five. They want for you to make changes based on how your business has changed over time or your customers have changed over time, industry standards have changed over time.

You need to review how your compliance program is actually working. Talk to your employees. Look at your culture. Take a good look at your compliance culture. Examine the controls that you have in place, and, of course, conduct periodic audits to see whether or not your program is effective. But most importantly, as I said, learn from your experience and make the changes that are necessary in order to best achieve compliance within your company.

Jose Garriga:

Thank you, Taylor. Matt, what are your clients asking about this guidance?

Matt Wetzel:

I think the top two questions I've received on the DOJ evaluation guidance, first, is this something that we need to incorporate into our internal compliance risk assessment process? Second, how exactly would we measure the effectiveness of a compliance program and document that measurement?

In the first one—how to incorporate it into the risk assessment process—I think Taylor has really answered that, which is, first, it's a document that's not intended for companies to directly pick up and put into their compliance program. It's really intended for prosecutors, as Taylor mentioned, but it also provides that perspective, the government perspective. It's that additional layer, additional lens, of areas of interest to incorporate into a risk assessment.

For example, the guidance goes into great detail about third-party risk management. How are you managing your distributors' and your wholesalers' interactions with your end-customers, if, for example, you're a manufacturer of a medical device or a pharmaceutical, like many of our clients. There's additional details in the questions that the guidance asks that can be useful in putting together your own risk assessment process. To answer the question, incorporate into the risk assessment process doesn't need to be word-for-word, but it does provide some good insight and some good information, as Taylor mentioned.

Second, how would you measure and document the effectiveness of the program over time? Again, Taylor talked about this as well. Has your program grown from one year, two year, to five years? Our recommendations typically would be to, first, match your strategic compliance plan with your commercial strategic plan. Your commercial plan, it's your business. That's where you're going to uncover the risks that the business currently faces and will face. It's the crystal ball, so to speak, to understand five years down the road what the company will be addressing or plans to address, and, so, you as compliance officers or as in-house counsel can plan for your compliance program to address those risks down the road.

In addition to the strategic plan, how do you measure year over year the change? That could be in the form of, say, an annual report or an annual reporting to the board of directors, to your senior management and to others about how the program currently meets the different elements of a compliance program, including the elements that are outlined in this guidance, so, showing consistent growth, showing that the strategic plan matches the commercial plan, and the like. All of this really flows together into the best approach for how to document your current and your potential future compliance program.

Jose Garriga:

Thank you, Matt. Just to wrap up, an open question for both of you. What are some notes that you might offer listeners for near-term actions to take regarding this guidance?

Taylor Jones:

I mean, like I said before, I think near term, you need to read through the guidance and then have a talk, engage in some detailed analysis of how your existing compliance program holds up given this new guidance. I think you want to assess your culture of compliance, determine is your risk assessment up to date. I think you want to look at any compliance challenges that you may have had over the last few years and ensure that you've been making changes and keeping your compliance program up to date as it relates to those specific types of challenges.

I also think you need to think about why has the DOJ released this guidance right now? Although they didn't provide much by way of explanation for that decision, I think, throughout the industry, we believe that it's possible that the DOJ is really planning to ratchet up its expectations for corporations as it relates to their compliance program. Definitely keep that in mind as you're assessing your risk at this time.

Matt Wetzel:

I think that's a great point, Taylor. That's one I hadn't thought of, which is, is this perhaps some sort of foreshadowing of additional government intervention? I think about, as I mentioned at the start of the podcast session today, DOJ has made a series of statements about partnering more with private sector compliance to prevent fraud. Perhaps this is their way of saying, "And if you want to partner with us, here are the different standards you need to meet. This is what we expect of a good partner in a fraud prevention compliance program." It's an excellent point.

I might say in addition, just following up and maybe being a little industry-specific here for the drug and device industry, that I think, down the road, we're starting to see greater interactions with our customers in terms of value-based arrangements, coordinated care, bundled payments that cover both procedures and products that go into those procedures. I think that sort of increased degree of interaction between medical product manufacturers—whether that's drugs or devices or biologics, diagnostic testing equipment, for example—the increased interactions between those manufacturers and their end-customers really means that both parties need to shore up their compliance programs even more. The risk level just increases—I don't want to say dramatically or significantly—but there is an increase in the amount of risk that companies and hospitals are willing to take on with these value-based arrangements. And, so, as risk increases, a compliance program needs to be fortified. I think this is a good tool to use to evaluate those programs as value-based arrangements and coordinated care become more of the norm.

Jose Garriga:

Thank you, Matt, thank you both. Listeners, you've been listening to Akin Gump health care and life sciences senior counsel Taylor Jones and Matt Wetzel. Thank you both for appearing on today's show and sharing this really great and thoughtful information.

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To learn more about Akin Gump and the firm's work in, and thinking on, health care industry compliance, look for health care and life sciences on the Experience or Insights & News sections on akingump.com or take a minute to read Taylor's and Matt's bios on akingump.com.

Until next time.

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