Answering the Existential Question: Is Our Compliance and Ethics Program Effective?

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Tom O'Neil leads BRG's Governance, Risk & Compliance (GRC) practice. He is a managing director with broad private and public-sector experience, including leadership roles in boardrooms and C-suites of companies in the health sector. He was joined by Robert (Rob) DeConti, a partner at King & Spalding and former Chief Counsel to the Inspector General at the US Department of Health & Human Services (HHS) Office of Inspector General (OIG).

Tom and Rob discussed Rob's career path and tenure at the OIG, his insight on compliance and ethics program guidance provided by the OIG, and key dimensions of program efficacy.

Tom: Hello, Rob. We are very grateful to be talking with you today. Thanks so much for carving out the time.

I'd like to kick off our conversation with reflections on your career path after you graduated from American University Washington College of Law.

Rob: During law school I had two jobs in the private sector, both with relatively small organizations. One was at a managed-care company where I worked in the general counsel's office. The other was as a summer associate for a small law firm representing healthcare clients. Both were wonderful experiences.

For most of my OIG career I worked as an attorney, focusing on healthcare fraud enforcement and compliance with US Attorney's offices across the country, negotiating global resolutions of often complex enforcement and litigation matters. During this time, I was mentored by Lewis Morris, who was a great leader throughout his tenure as chief counsel.

In 2007 I decided to shake up my career and join the newly established Medicare Fraud Strike Force. While there, I worked in collaboration with the DOJ [US Department of Justice] and other agencies on healthcare fraud matters in the Southern District of Florida. From there, an opportunity to apply for management came at OIG, and I rose steadily through the ranks with more responsibility until eventually becoming chief counsel. So, I started my time at the OIG as a law clerk and left as the chief counsel.

Tom: That was quite a journey! What is the relationship between the inspector general and chief counsel?

Rob: As the chief counsel, you are responsible to clients on a day-to-day basis in a way that is unlike other government attorneys. The goal is to figure out how to help a client organization achieve its strategic objectives. In other words, what is the optimal path? It is valuable and really satisfying work.

Tom: And all of this is under the glare of congressional oversight, similar in some ways to the oversight of a board of directors or governing body in the private sector.

Rob: No question, there are many Capitol Hill eyes on HHS, and many members of Congress have a keen interest in the OIG's work—and varying points of view on what should be prioritized. In my view, the HHS OIG is the crown jewel of the federal inspector general community, and it was a wonderful opportunity to serve as chief counsel.

Tom: One thing I want to explore with you is the concept of enforcement and education. While enforcement is a critical dimension of the OIG's mission, it has also led the way in providing guidance and educational resources to the healthcare community. What was the genesis of those initiatives?

Rob: I can't speak for the OIG today, but as a former leader I can say that the OIG's external focus stems in large part from the sheer volume of funds that flow out of HHS. The scale of its resources and range of programs is vast. OIG extends its range by enlisting partners throughout the world. Nearly everything the OIG does relies on partnerships. Offering guidance and best practices as a lever to make positive change in the world, even with limited resources available, has been the genesis of OIG external guidance for years.

Tom: Those partnerships have included private-sector organizations, which is distinctive.

Rob: I agree. Some federal agencies that have regulatory authority are criticized for being disassociated with the industry they regulate, but that has never been the case with the OIG at HHS. Not everyone is going to agree with a regulatory agency all the time, but engagement engenders trust.

Tom: Are there discussions about compliance program effectiveness across the top level of the government? And between agencies?

Rob: When I think about coordination between federal agencies, it is hard to imagine two agencies coordinating more than HHS and DOJ in fighting healthcare fraud, waste, and abuse. It is a marriage that has stood the test of time.

Tom: How has the OIG's compliance and ethics program guidance evolved?

Rob: When I started with the OIG in the late 1990s, I spent most of my time negotiating corporate integrity agreements with hospitals. At that time maybe half of hospitals had a compliance program in place, and that reality informed our early guidance. The first iterations of "The Seven Elements" focused on establishing, and what it meant to have, a program.

Over time we shifted our focus to include what makes a compliance program successful and investing in the leadership of the organization. Most recently, the latest phase of guidance has focused on what separates outstanding programs from the rest. Modern-day guidance is a culmination of thirty years of industry observations and lessons.

Tom: When thinking about an exemplary compliance program, what key features or hallmarks come to mind?

Rob: Data and use of data analytics to show how they deliver outstanding patient care comes to the top of mind. An organization that uses data in a sophisticated manner will be well placed when the government comes knocking. I also think a program sets itself apart when its compliance function and sales and business operation teams have access to the same data.

Tom: It sounds like you're suggesting that it is essential for the data to be viewed with an enterprise mindset rather than siloed?

Rob: Yes. And speaking of an enterprise mindset, the best programs connect compliance and clinical quality. If I were to lead a healthcare organization, I would have pride in the outstanding care that we deliver and the difference we can make in patients' lives. It would be imperative for all business units and corporate functions to align with that mission—including, of course, the compliance and ethics program.

Tom: The role of a chief compliance and ethics officer is multidimensional and, in a sense, nuanced.

Rob: Yes. Being independent—but also connected—is a challenge that both a chief compliance officer (CCO) and an inspector general face. The best leaders leverage that dynamic tension and establish an effective equilibrium. If you focus on being overly independent, you lose the ability to get the truth from people and understand risk areas. On the other hand, if you are too connected, you may lose your independent vantage point and have difficulty reporting with objective and fully informed authority.

Tom: It is often easier said than done! We talked briefly about boards—what is your view of the duty of a board or governing body in overseeing an organization's compliance and ethics, and quality of care, programs?

Rob: Boards play a key role in leading all aspects of the organization, including the compliance function. Everyone must ensure the directors feel equipped to ask the requisite questions to fulfill their fiduciary responsibilities. Leaders should report to the board frequently, and the board should ask questions about the composition of the compliance team and if more support or additional tools are needed to help the compliance function succeed.

Tom: If you were to join a board, how would you collaborate with the CCO?

Rob: I would focus on:

- The risk assessment—and ask the team to show its work. How did they go about completing the assessment?
- Our twelve-month plan and beyond. What measurements are in place to assess success against our goals?
- Data. What access does the team have, and how does it utilize the information?
- Touchpoints with clinical quality. How does the team view that relationship?

Having curiosity and asking questions are vital responsibilities of a board member.

Rob DeConti
Partner
King & Spalding

Tom: Reflecting on the latest OIG guidance, as well as your own observations over many years, how can early phase startups establish and maintain a culture of compliance and develop a program?

Rob: With a young company, we often see a varied understanding of regulations around the healthcare industry. I have observed that not all organizations—and particularly startups—realize how regulated this space is. Many organizations could benefit from guidance. My first piece of advice would be to learn what you do not know and understand that new entrants will have a higher risk tolerance as they move to build market share. You can have various levels of risk tolerance, but you will benefit from a strong understanding of what you are about to undertake.

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Tom: One thing I tell boards and C-suite members is that if you plan to participate in a government-sponsored healthcare program, you must understand the key differences between government and commercial contracting. Both the rules of engagement and key stakeholder expectations are very different.

Rob: That makes perfect sense, and your advice is correct. One of the most interesting reactions I saw to the General Compliance Program Guidance was that readers picked up the fact that if you take out healthcare and swap in another industry where human lives are at stake, the principles within are relevant and useful. It was gratifying that the OIG did not have to state that in the publication, but readers interpreted it.

Tom: Data analytics has become a common term, but now we are all talking about artificial intelligence (AI). How might AI affect the fields of compliance, ethics, and quality care moving forward?

Rob: When I started my career in the late 1990's, the pneumonia "upcoding" cases were coming through the system. Many of those cases resulted from consultants who went into hospitals and said they were going to help find support in medical records for higher-paying patient diagnostic-related groups (DRGs), and as a result the hospitals could pay them a percentage of the increased Medicare reimbursements. The consultants left a trail of destruction when the government came, and hospitals had to deal with the aftermath.

I worry that you can swap out those consultants with the AI vendors you see today, selling a solution that is going to help the hospital bill, code, or any one of the many things the technology can do. The government will focus on whether the new technology is contributing to harm.

Technology does hold the promise of making care more efficient and accurate, but the compliance and legal functions must understand what is being employed and assess risks. Compliance should be on equal footing when it comes to data and employment of any new technology or AI. In healthcare, everything old is new again, and there are many lessons to be learned from the early cases involving consultants, incentives, and electronic medical records.

Tom: I think that is a fair analogy. Thanks again for sharing your insights and reflections today, Rob. And best of luck with your new chapter at King & Spalding.

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