

DOJ Compliance Program Evaluations Present A Challenge For Compliance Officers

By Richard Kusserow | November 5, 2020

Key Points:

- **New DOJ Compliance Program Guidance for prosecutors replaced DOJ Compliance Expert position**
- **Few health care organizations can expect to meet the standards**
- **Mock DOJ Compliance Program Evaluations might be useful**

In recent years, the U.S. Department of Justice (DOJ) has issued a series of policies designed to incentivize companies to invest in programs that ensure employees do not violate the law. The stated goals under the DOJ's leniency policy, which gave consideration to effective compliance programs, were to have more internal consistency, clear guidelines, and metrics related to how prosecutors would evaluate companies on the criteria of voluntary disclosure, cooperation, and remediation.

In 2015, the DOJ moved to bolster expertise by hiring a former Compliance Officer to advise prosecutors on assessing compliance programs of companies being investigated by the agency. In 2018, the DOJ formally announced that it had discontinued the use of the compliance counsel position and called it "shortsighted;" instead, it moved in favor of training a cadre of prosecutors to address compliance program effectiveness. The DOJ developed a training program addressing compliance programs generally, as well as issues specific to each section and unit. In a 2018 Corporate Compliance and Enforcement Conference, Assistant Attorney General Brian A. Benczkowski stated that "[O]ne constant is that every case will at some stage require a deep look into the sufficiency and proper functioning of the subject company's compliance program. As companies continue to grow in size, scope and complexity, and as international business becomes the norm rather than the exception, compliance is of ever greater importance in ensuring that companies operate efficiently and within the bounds of the law."

One result of these changes has been an increase in the number of health care fraud attorneys who work on corporate cases, becoming experts in health care industry compliance. As part of this new effort, the DOJ developed Compliance Program Guidance documents. The 2019 DOJ Compliance Program Guidance (2019 Guidance) set the stage with 179 questions that prosecutors should use to decide the effectiveness of a company's compliance program. In following year, the DOJ issued an updated Compliance Program Guidance (2020 Guidance). The stated purpose of the 2020 Guidance is to assist prosecutors in making informed decisions about "whether, and to what extent, a company's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and

(3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).”

The 2020 Guidance is another major step forward in the process of evaluating compliance programs. The 2020 Guidance extended the use from just the Criminal Division to all of the DOJ, including the Civil Division, where most health care cases are handled. The 2020 Guidance nearly doubled the number of questions and factors prosecutors must consider and focused on the following overriding questions:

1. Is the corporation’s compliance program well designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
3. Does the corporation’s compliance program work in practice?

The hundreds of questions and factors related to these three areas create a great challenge for Compliance Officers in trying to convince prosecutors that their compliance program meets these standards. Since the DOJ would have already determined that the organization has violated federal law, it is reasonable to expect that the DOJ will likely distrust representations from the company or the Compliance Officer if there is credible unsupported evidence. To be acceptable, evidence provided must be viewed as credible and trustworthy, with preference given to evidence that has been developed by independent parties. Credibility also will depend on sources of information, conditions of data collection, reliability of measurement, validity of interpretations, and quality control procedures followed.

Compliance Officers may find a mock DOJ Compliance Program Evaluation (Mock Review) useful. When Strategic Management performs such reviews, they differ significantly from a traditional Compliance Program Effectiveness Evaluation or Gap Analysis. Those reviews involve a full document examination, many interviews, and a site visit that result in a comprehensive report. The Mock Review is a more limited consulting engagement where the work is conducted in collaboration with the company’s Compliance Officer to focus on identifying ways to better document the compliance program’s operations. The results from the review are action items to fortify and fix noted weaknesses, which can be used as the foundation for the company’s annual Compliance Office workplan. In addition, this has the added benefit of evidencing continued improvement and advancement of the compliance program.

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