

Compliance Today – September 2020 DOJ updates its guidance on corporate compliance programs

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On June 1, 2020, the Criminal Division of the United States Department of Justice (DOJ) issued an update to its guidance in the *Evaluation of Corporate Compliance Programs* (Guidance) used by prosecutors to probe corporate compliance programs.^[1] DOJ's Fraud Section first released the Guidance in February 2017,^[2] incorporating principles from the DOJ's *Justice Manual*. Prior to the 2020 revisions, DOJ revised the Guidance in April 2019, expanding its applicability to the entire DOJ Criminal Division.

The "Principles of Federal Prosecution of Business Organizations" in the DOJ's *Justice Manual* describe specific factors that prosecutors should consider when conducting an investigation of a corporation, determining whether to bring charges, or negotiating plea or other agreements. These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one."^[3]

The 2020 Guidance updates appear to reflect DOJ's recent experience and feedback from compliance and business communities that have shaped its current approach to evaluating compliance programs. The updates reveal DOJ's evolving considerations of key compliance themes such as the evolution of compliance programs over time, the adequacy of compliance program resources, the effectiveness of training and communication programs, the need for monitoring of third parties, and considerations related to foreign-law compliance.

Healthcare companies intending to use the Guidance in assessing their own compliance programs would do well to understand its purpose. The Guidance is intended to assist prosecutors in making informed decisions as to whether, and to what extent, a corporation's compliance program was effective at two points in time: (1) at the time of the offense and (2) at the time of a charging decision or resolution. Prosecutors will use such a decision to determine the appropriate form of any resolution or prosecution; monetary penalty, if any; and compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).^[4]

Previous versions of the Guidance instructed prosecutors to assess the effectiveness of a company's compliance program by answering three questions:

1. Is it well designed?
2. Is it implemented effectively?
3. Does it actually work in practice?

The new Guidance revised the second question. Instead of solely focusing on the conclusion—whether the program is implemented effectively—the updated Guidance puts more importance on the process—whether the

program is “adequately resourced and empowered to function effectively.”

The Guidance is not a checklist or a compliance program best practice guide. In fact, it notes that the sample questions and topics discussed are not a checklist or a formula and may not even be relevant in some cases. The goal of the Guidance’s questions is to assess whether the compliance program being presented to the prosecutors established four basic pillars: credibility, measurable results, accountability, and continuous improvement.^[5] Keeping the intent of the Guidance in mind and armed with the updated information in the new version, healthcare providers should reassess the effectiveness of their compliance programs in preventing, detecting, and correcting misconduct in their organizations.

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