

Insights

How Does My Compliance Program Measure Up?

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While the goal of any organization is to avoid investigation by government agencies altogether, the reality is that health care providers operate in a highly regulated industry resulting in greater risk of encountering an enforcement action at some point. Therefore, it is imperative to consider how an organization's compliance program will be assessed should an enforcement action arise. On June 1, 2020, the United States Department of Justice's Criminal Division ("DOJ") updated its 2019 publication, "Evaluation of Corporate Compliance Programs," to further clarify its continuing guidance on how criminal prosecutors are instructed to assess such programs implemented by health care organizations. The 2020 update makes four important modifications to the DOJ's evaluation of corporate compliance programs ("Program"):

1. The DOJ clarified the importance of Program funding and function while also considering the many corporate factors including size, industry, regulatory landscape, and both internal and external factors, all of which impact Program implementation.
2. The DOJ placed increased significance on whether a Program is adequately resourced and empowered to function effectively. Specifically, Program effectiveness is to be measured based on commitment at all levels of the company including both senior and middle management.
3. The DOJ further emphasized the importance of maximizing the allocation of resources to implement necessary Program infrastructure and to require meaningful access to relevant data sources that will facilitate Program oversight and evaluation.
4. The DOJ placed increased value on whether a company routinely reviews and adapts its Program based upon lessons learned from its own conduct and/or that of other similarly-situated companies.

The DOJ's updated guidance continues to be divided into three parts:

- Part I discusses the key components of a well-designed Program, specifically risk assessment, policies and procedures, training and communications, reporting and investigation, mergers and acquisitions, and third-party management.
- Part II reviews the key elements of effective Program implementation including Program commitment throughout the organization, Program autonomy and resources, and the various incentives and disciplinary measures used to promote quality care, lawful and ethical business relationships, and accurate billing practices.



- Part III focuses on the metrics used by prosecutors in evaluating Program effectiveness and its capacity to attain continuous improvement, periodic risk assessment, investigations of actual or suspected misconduct and the steps necessary to mitigate and correct confirmed offenses.

In our continuing efforts to represent and advise our clients regarding the “effectiveness” of their corporate compliance programs, we find this updated DOJ guidance to be instructive. If you have any questions or require additional information regarding these and other resources that Integrity Health Strategies and Krieg DeVault can offer to you in the ongoing development of your compliance program efforts, please contact Susan E. Ziel or Andrew W. Breck for more information.