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Insights

DOJ Releases Guidelines for Evaluating Effective Compliance Programs

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The United States Department of Justice's ("DOJ") Fraud Section recently published guidelines ("Guidelines") it will use when determining whether to bring charges against health care entities or individuals. While the Guidelines in no way represent an absolute defense against potential federal or state prosecution, they provide insight into the DOJ thought process and give health care entities a framework for building or revising compliance policies and protocols.

The Guidelines are not prescriptive, but are rather a series of questions about compliance programs delineated under 11 different topic headings. The 11 topics and underlying questions seek, in a general sense, to determine the extent to which an organization's compliance program is robust, effective, and embedded within its culture from top to bottom. The 11 different topics include:

1. Analysis and remediation of the underlying misconduct
2. Senior and middle management
3. Autonomy and resources
4. Policies and procedures
5. Risk assessment
6. Training and communication
7. Confidential reporting and investigation
8. Incentives and disciplinary measures
9. Continuous improvement, periodic testing, and review
10. Third-party management
11. Mergers and acquisitions

Health care providers are not required to follow the Guidelines. In fact, the DOJ clarified under the Guidelines that these topics and questions "form neither a checklist nor a formula," and that some may be more relevant to the DOJ under certain facts or circumstances than others. The Guidelines are merely published as a means of self-evaluation for revision of current compliance practices in order to withstand DOJ scrutiny during potential investigations of noncompliance or misconduct.

Please contact Brandon W. Shirley or Consultant Susan E. Ziel if you have questions or concerns about your organization's health care compliance program.