

OIG's New Comprehensive General Compliance Program Guidance

The Department of Health and Human Services' Office of Inspector General (OIG) published its General Compliance Program Guidance (GCPG) on November 6, 2023. The GCPG is a centralized resource for health care industry stakeholders to reference voluntarily in their efforts to self-monitor compliance with applicable laws and program requirements. Below are some of the key highlights of the new GCPG.

Five Main Areas of GCPG

Laws & Regulations



Adaptations for Size of Company



OIG Resources



7 Elements of a Compliance Program



Other Considerations



CCO & Compliance Committee



- Reports directly to CEO or Board.
- Does not report to Legal or Finance.
- Advises CEO, Board, and Senior Leaders on Compliance risk and operation of the Compliance Program.

CCO

- Purpose is to aid and support the CCO in implementing, operating, and monitoring the Compliance Program.
- Comprised of leaders of operational and supporting departments.



Compliance Committee

- Indicators of success include: engagement and substantive discussions, accountability, establishment of work plans, and mitigation of risk.
- Members' participation and contribution should be considered in performance evaluation and compensation.

Training & Education

- An annual training plan should be developed and should incorporate material addressing concerns identified in audits or investigations.



- Board members, employees, and contractors should receive training at least annually on the Compliance Program and potential risks.
- Targeted training specific to role should also be developed and assigned.
- Education should not be limited to formal training.

Enforcing Standards

For a Compliance Program to be effective, there should be consequences for noncompliance as well as incentives for compliance.

Stick



- Consequences may be educational or remedial and non-punitive, or punitive, or both.
- Consequences should be imposed on a fair and equitable basis and consistently applied.

Carrot



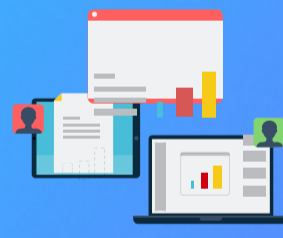
- Excellent compliance performance or significant contributions to the Compliance Program could be the basis for additional compensation, significant recognition or other forms of encouragement.

Risk Assessment and Monitoring

There are a number of new "shoulds" in risk assessment and monitoring.



Formal Risk Assessment At Least Annually



Use of Data Analytics



Horizon Scanning for New Risks via Review of Enforcement Actions, Regulatory Changes, etc.

Small vs. Large Company



Compliance Programs may be structured differently depending on the company's size. Companies should right-size their Compliance Program to meet the organization's needs.

Quality and Safety

A Compliance Program should not be viewed as an isolated function, but rather as an integral part of an organization's overall quality and safety efforts.

The Compliance Program should include and address quality and patient safety compliance risks.



The CCO should develop working relationships with clinical and quality leadership, sharing information and advising on compliance matters.



The CCO should be informed about any quality audits and incidents and have the resources to conduct quality compliance audits.

Private Investment



The increasing involvement of private equity and other forms of private investment (such as venture capital groups) in the healthcare sector has introduced novel concerns regarding incentive structures and familiarity with healthcare regulations. Comprehending the intricate legal landscape governing the healthcare industry and the significance of a robust Compliance Program is paramount.