

epsilon
life sciences

CLIENT ALERT

10 Key Quotes and Takeaways from the Office of Inspector General's (OIG) 2023 General Compliance Program Guidance

- > Earlier this month, the Department of Health and Human Services Office of Inspector General (OIG) released its “General Compliance Program Guidance” (GCPG) as a first step to modernizing its healthcare compliance resources. While specific language and format have changed, notably the OIG retains its "7 Elements" structure that the industry has grown accustomed to in the twenty years since the last major OIG guideline.
- > Starting in 2024, OIG plans to publish segment-specific CPGs for different types of participants in the healthcare industry, including the pharmaceutical industry.
- > In this document, we have identified key quotes and takeaways from the 2023 GCPG document – some call-outs reflect notable updates to OIG's previous guidance documents; others reflect good reminders of OIG's areas of priority. We'd recommend you read the whole document for more information as it's a good read!
- > Also note that OIG makes clear that the GCPG is “voluntary guidance” and is not binding on any individual or entity.

1. Accessibility, Readability, and Leadership Commitment of Written Standards



Besides being **accessible**, the code, policies, and procedures also should be **comprehensible** by all relevant individuals (e.g., **translated** into other languages, where appropriate, and **written at appropriate reading levels**).

...

CEOs can demonstrate their embrace of the organization's commitment to compliance with a **signed introduction in the code**...the board also may wish to include a signed endorsement or a similar written statement.



The OIG follows its own direction in this 2023 GCPG, which reflects a more “user-friendly” and accessible format than previous guidance documents.

Element 1: Written Policies and Procedures

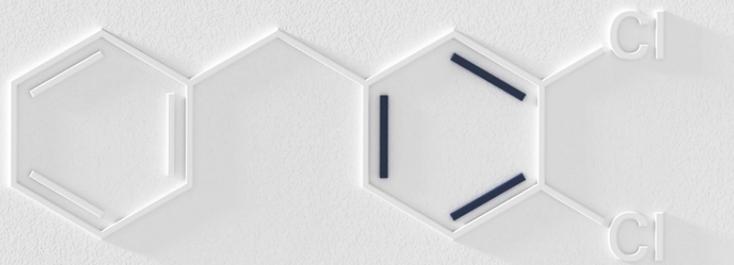
2. Clear Statement of Recommended Compliance Officer Reporting Lines



[T]he compliance officer **should not lead or report to the entity's legal or financial functions**, and should not provide the entity with legal or financial advice or supervise anyone who does. The compliance officer **should report directly to the CEO or the board**.



While previous OIG guidance emphasized “direct access” to the CEO and board, this latest direction is a firmer communication regarding specific compliance officer reporting lines.



Element 2: Compliance Leadership and Oversight

3. Compliance Committee Engagement and Indicators for Committee Success



Expectations for **regular, diligent member attendance** at Compliance Committee meetings should be **set by the board and enforced by the CEO**. Member **attendance, active participation, and contributions** should be included in each member's **performance plan** and **compensation evaluation**.



The 2023 GCPG section on Compliance Committee duties and expectations can be a helpful tool for Compliance officers to drive active and consistent support from your committee.

Element 2: Compliance Leadership and Oversight

4. Active Board Oversight Over the Compliance Program



[T]he board should assure that the **compliance officer's stature is commensurate with their responsibilities** and those of **other entity senior leaders**...

The board also should regularly review whether...the compliance program ha[s] **sufficient staff and resources** for an entity of its size [and] complexity...

...meet with the compliance officer...**no less than quarterly**.

New board members should receive **training on their governance and compliance oversight roles promptly** after joining the board.



In line with more recent government communications, the GCPG emphasizes Board oversight over the compliance program, its resourcing and the stature of the Chief Compliance Officer.

Element 2: Compliance Leadership and Oversight

5. Annual Training Plan with Multifaceted Education Models Tailored to the Company and Reinforced by Business Leadership



The compliance officer, with the support and aid of the Compliance Committee, should develop and coordinate a **multifaceted education and training program specific to the needs of and risks** presented by the entity.

...develop an **annual training plan** that includes... training topics [and] target audience.

...consider [having] various committee members and **entity leaders deliver compliance training in meetings and settings where they already appear**. This will help normalize compliance as an **integral part of the entity's culture**.



Recent guidance emphasizes risk-based effective training – the GCPG provides several education models to consider, including easily accessible FAQs, standing compliance topics at regular meetings, columns in company newsletters, compliance video clips, and more.

Element 3: Training and Education

6. Prioritize Relevant and Clear Communications to Employees, Both in Language and in Preferred Communication Styles



Entity personnel should be informed about the ways they can reach the compliance officer directly (e.g., via email, telephone, messaging). This information also should be **posted in commonly frequented physical and virtual spaces**. The compliance officer may wish to occasionally poll entity personnel on means of reaching the compliance officer to ensure that diverse personnel (including personnel of **different generations** and **communication preferences**) have familiar means of communicating with the compliance officer.



The GCPG reiterates the importance of available lines of communication to the compliance officer through several clear channels, as well as the importance of not deterring reports of concerns by maintaining a non-retaliation policy.

Element 4: Effective Lines of Communication with the Compliance Officer and Disclosure Programs

7. Both Incentives and Consequences Are Important to Enforcing Compliance



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

OIG encourages the compliance officer and the Compliance Committee to **devote time, thought, and creativity** to the compliance activities and contributions that the entity would like to incentivize.



OIG adds to the growing body of behavioral compliance recommendations to incorporate “carrots” and “sticks” to induce good behavior. Examples of behaviors to incentivize include where an individual or team: develops a process that reduces risk or enhances compliant outcomes; suggests a method of attaining a strategic goal with less risk; mentors colleagues on compliance; performs as the compliance representative within their team.

**Element 5: Enforcing Standards:
Consequences and Incentives**

8. “Risk Assessment” Officially Added to the “Auditing and Monitoring” Element, Emphasizing a Risk-Based and Data-Informed Approach to Compliance Activities



Periodic compliance risk assessments...should be conducted **at least annually**.

A formal compliance risk assessment process should pull information about risks from a variety of **external and internal sources**, evaluate and prioritize them, and then decide which risks to address and how to address them. The **Compliance Committee should be responsible** for conducting and implementing the...risk assessment.

[C]onsider using **data analytics**...to identify compliance risk areas. All entities...**should have access to the data they generate**, either directly or through a third party.



While many companies utilize risk assessments to inform prioritization of compliance resources, the GCPG provides helpful details on the government’s expectations for formal annual risk assessments and a company’s review of its own data to identify risk.

Element 6: Risk Assessment, Auditing, and Monitoring

9. Periodic Assessment of the Compliance Program's Effectiveness

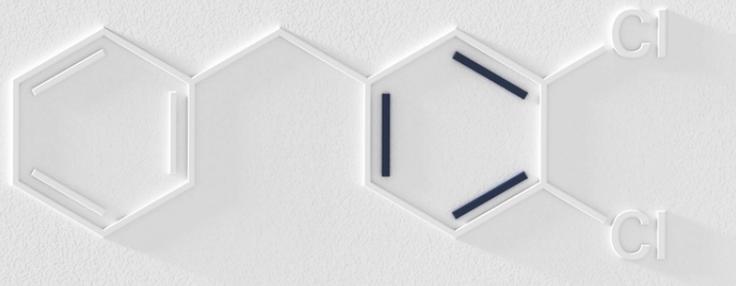


Entities also should **periodically assess the compliance program's effectiveness**. The review should include an assessment of how effective **each element** of the compliance program is.

The board should direct the entity to perform the compliance program effectiveness review and have the reviewers report their findings and recommendations directly to the board.



OIG and other government agencies have stressed that companies periodically assess the “effectiveness” of their compliance programs, and not implement static programs that do not evolve with the organization.



Element 6: Risk Assessment, Auditing, and Monitoring

10. Concerns Will Arise; Documentation and Corrective Action is Key to an Effective Compliance Program



No matter how strong an entity's commitment to compliance or how effective the policies and procedures, training, and risk assessment, **it is inevitable that a compliance officer will receive audit or monitoring results that raise concerns** or receive a report through the disclosure program that requires investigating.

Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the entity.

Regardless of the size or severity of the violation being investigated, a **contemporaneous record** of the investigation should be maintained...



The OIG recognizes that effective compliance programs will uncover potential misconduct, but the GCPG stresses that companies promptly investigate and document remediation efforts and report certain infractions to the government. OIG recommends documentation in a compliance log which includes the allegations, interview notes, investigation results, and corrective actions undertaken, among other items.

Element 7: Responding to Detected Offenses and Developing Corrective Action Initiatives

11. Bonus Takeaway: “Follow the Money”

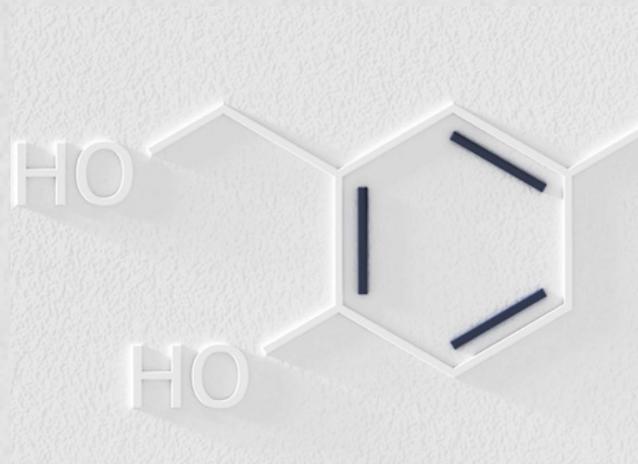


One of the best ways to identify fraud and abuse risks is to **follow the money**.

In an increasingly complex health care ecosystem, understanding how funds flow through business arrangements and the varying incentives created by different types of funding structures is key to unearthing potential compliance issues, implementing effective monitoring, and identifying preventive strategies.



The adage “follow the money” is common in risk management, but many organizations continue to spend valuable compliance resources tracking down minor items without a risk-based analysis.





Steven Klimberg, JD, MBA

sklimberg@epsilonlifesciences.com
609.923.8764



Liz Prinzi, MPP

lprinzi@epsilonlifesciences.com
718.404.8267



Matthew Chandler, JD

mchandler@epsilonlifesciences.com
804.223.6933



Casey J. Horton, CFE

chorton@epsilonlifesciences.com
312.316.9294



J. Mark Farrar, CPA, CFF, CFE

mfarrar@epsilonlifesciences.com
404.644.1056



Saul B. Helman, MD, MBA, BS

shelman@epsilonlifesciences.com
317.294.1228