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CLIENT ALERT

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

> The Department of Health and Human Services Office of Inspector General (OIG) released its "General Compliance Program Guidance" (GCPG) in November 2023 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 focused on implications for boards of healthcare organizations and 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.

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1. Setting the Tone

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

The board can support setting the tone around the importance of compliance through a signed endorsement of the Code of Conduct included directly in the Code. Additionally, the board should review the Code on an annual basis and capture this review and endorsement in meeting minutes. The board's endorsement should be communicated to the organization, reinforcing their oversight responsibilities.

Note: in larger organizations, the board may delegate this and all other responsibilities related to the compliance program to a sub-committee. Throughout this paper, the term "board" can be interchangeable with "board sub-committee." The only additional consideration for larger boards, not discussed later on, is that the compliance officer should report to the full board at least once a year on the compliance program.

In large, complex, multi-national organizations that are owned or controlled outside of the U.S., the parent board should receive regular reports from the U.S. compliance officer. In many cases, the U.S. operating division/ company of an international company that is owned and operated from outside the U.S., may have a board that is comprised of company executives to have oversight of local matters. In this case, consideration should be given to engaging an independent board member on this "management" board with knowledge of federal and state healthcare requirements to support the oversight of compliance within the U.S.

2. Compliance Leadership and Oversight

> Boards and senior leadership are vital to effective compliance programs. An effective compliance program reduces and mitigates risk, provides patients safe and high-quality care, and saves costs. To be effective, a compliance program should have a board and senior leadership that understand its value and are committed to its success. One of these senior leaders should be the Compliance Officer.

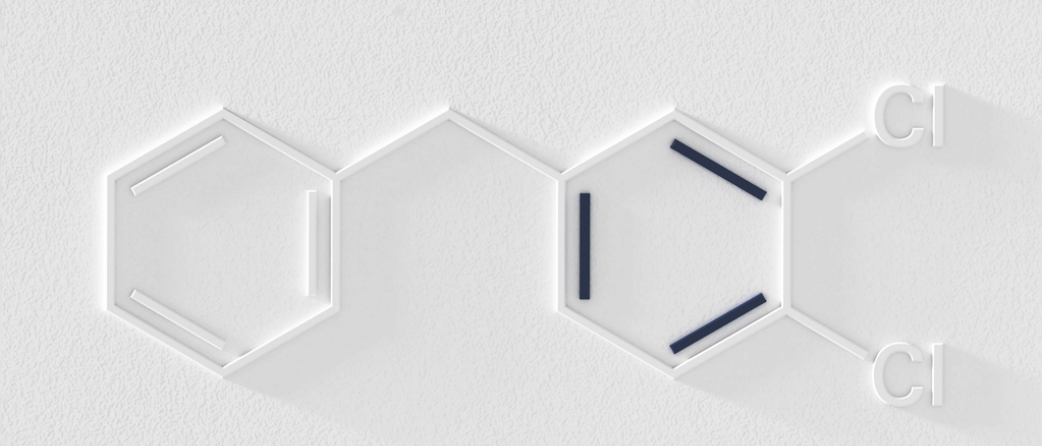
Boards should have direct oversight of the Chief Compliance Officer – a role in itself that should directly report to the CEO and be at a senior enough level to be able to influence strategy of the company.

The board should also be well briefed on the compliance program and demonstrate commitment to its success. Their oversight responsibilities should cover risks for the company, assurance functions, the healthcare compliance program including the Compliance Committee and the Chief Compliance Officer. Oversight goes beyond just the reviewing the effectiveness of assurance functions, but also includes review of the performance of business leaders for those functions and whether their incentive and performance metrics appropriately reflect their responsibilities and participation in assurance functions.

3. The Compliance Officer

> The Compliance Officer's primary responsibilities should include advising the CEO, board, and other senior leaders on compliance risks facing the entity, compliance risks related to strategic and operational decisions of the entity, and the operation of the entity's compliance program.

The Compliance Officer's reporting relationship to the board should be direct and should focus on "the implementation, operation, and needs of the compliance program, the compliance risks the entity faces, and the methods through which the entity is addressing or can address those risks." The guidance emphasizes that a Compliance Officer's "sole responsibility should be compliance." Compliance Officers should directly report to the CEO and be at a senior enough level to be able to influence strategy of the company. The Compliance Officer should chair the Compliance Committee.



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4. The Compliance Committee

> The tone for all aspects of the Compliance Program, including the Compliance Committee, should be established and maintained by an organization's leadership, including the board and the CEO. 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. In their communications with individual committee members, the board and the CEO should regularly convey the importance of, and their interest in, the member's Compliance Committee responsibilities and participation.

The Compliance Officer should report to the board on the participation and contribution of the Compliance Committee members. The compliance officer should also identify any adjustments needed to improve the performance of the Compliance Committee – including "revisions to committee charter, scope, or membership, expectations regarding membership, and methods of ensuring Committee and member accountability."

The board is responsible for overseeing the Compliance Officer and the compliance program including the Compliance Committee, whereas the "Compliance Committee's purpose is to aid and support the compliance officer in implementing, operating, and monitoring the compliance program." The board "should strive to ensure that Compliance Committee members correctly understand their role."

Boards should also ensure that the:

1. Compliance Committee's decisions and activities are appropriately implemented and performed
2. Board understands and evaluates how the Compliance Committee addresses risk

5. Board Compliance Oversight

> Boards should pay attention to the Commission's Guidelines because federal courts consult when determining criminal sentences. Corporate boards also have a fiduciary duty of care, which requires that boards assure that 'information and reporting systems exist in the organization that are reasonably designed to provide to senior management and to the board itself timely, accurate information to allow management and the board, each within its scope, to reach informed judgments concerning... the corporation's compliance with the law...' In re **Caremark, 698 A.2d 959, 970 (Del. Ch. 1996)**.

The board must oversee the Compliance Officer, the Compliance Committee, and the overall compliance risk environment that the organization faces through regular (at least quarterly) reports from the Compliance Officer.

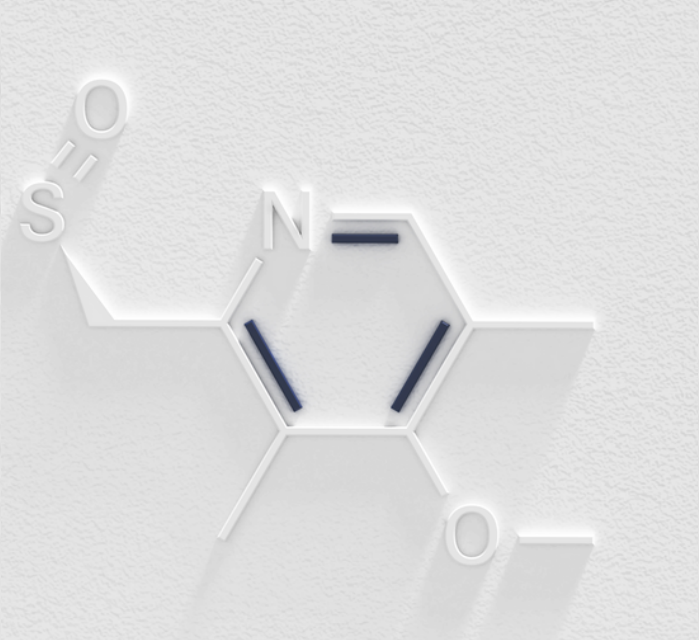
The board must ensure that the Compliance Officer has the authority, seniority, independence, and resources to design, implement, maintain, and evaluate the effectiveness of the compliance program.

A key component of an effective compliance program is a risk assessment and risk mitigation program that should be conducted and implemented by the Compliance Committee. The board's oversight of the risk assessment and related risk mitigation plans supports their oversight function.

6. Executive Sessions

> As OIG has stated in the **Practical Guidance for Health Care Boards on Compliance Oversight**, '[s]cheduling regular executive sessions creates a continuous expectation of open dialogue, rather than calling such a session only when a problem arises, and is helpful to avoid suspicion among management about why a special executive session is being called.'

Every board meeting agenda that includes compliance should have an executive session with the Compliance Officer, without non-board members present. This session allows for regular, open discussions regarding the compliance program, reinforces the seniority and independence of the Compliance Officer, and provides an opportunity for compliance discussions when issues arise at the board level.



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7. Board Communication

> The board should take every opportunity to communicate to each of its audiences its commitment to compliance. Every board has a variety of audiences, which could include entity leaders, personnel, individual owners, shareholders, customers, patients, payors, Federal and State Governments, and the public.

The board should have a proactive communication plan supported by the Compliance Officer (in terms of content, audience, and timing). The board, or a representative of the board, should communicate with key stakeholders across the organization on the importance of compliance and the expectations of the board. Examples of opportunities to actively communicate the board's position on compliance include:

- Board member(s) attending a Compliance Committee meeting
- Board member(s) meeting with the compliance team
- Board member(s) meeting with the executive committee/ leadership team
- Board member(s) attending a town hall meeting

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8. Training and Education

> All board members, officers, employees, contractors, and medical staff (if applicable) of the entity should receive training at least annually on the entity's compliance program and potential compliance risks.

Initial formal training of board members on their responsibilities as it relates to compliance should include training on:

- Their fiduciary responsibility as it relates to compliance
- Their role in governance and oversight of the compliance program
- The compliance risks faced by the organization
- Federal and state healthcare requirements

Additional periodic training of board members should be arranged when needed, including when there are changes to federal and state healthcare requirements.

Any new board member should receive the initial training promptly (ideally within 30 days).

In addition, part of the compliance training for company employees should include training on the compliance program, federal and state standards applicable to the company, and board governance and oversight of the company.

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9. Compliance Program Effectiveness Review

> 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. Depending on the entity's resources and recent compliance history (e.g., a large compliance failure or a series of events the compliance program did not identify and address as risks), the board may want to consider retaining an outside expert to conduct the review.

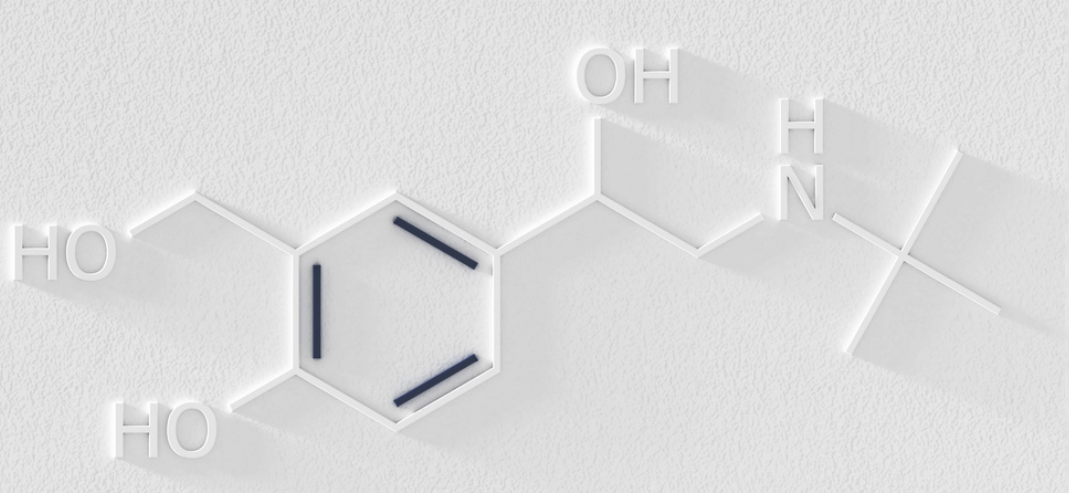
The OIG has published a toolkit – **Measuring Compliance Program Effectiveness** – which provides a framework for evaluating a compliance program. At a minimum, this framework can help guide a self-evaluation of the program. The Department of Justice's **Evaluation of Corporate Compliance Programs** can also help frame a review. Additional resources that should be considered include the Federal Sentencing Guidelines and the various OIG guidances related to board responsibilities as they relate to compliance oversight. These guidances point towards what should be considered in an evaluation of the effectiveness of the compliance program. Though, as the OIG has noted, these guidances are not intended to be checklists and that "[u]sing all the tools or many of them is impractical and not recommended." The tools applied should be based on the organization and their needs.

When considering an outside vendor to conduct a compliance program effectiveness review, the board should look to an entity/ individual who has expertise in compliance with federal and state healthcare requirements and FDA requirements and is considered an expert in this space.

10. Quality

> The board should require regular reports from senior leadership responsible for quality and patient safety and from the compliance officer on oversight of quality and patient safety compliance. The board should receive regular reports on the system of internal quality controls, quality assurance monitoring, patient safety, and patient care.

This section of the guidance focuses on the provision of healthcare, however, quality within pharmaceuticals and medical technology companies is equally important in the context of patient safety. The Compliance Officer should engage the quality assurance function and ensure that function reports to the board at least once a year.



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11. How Epsilon Life Sciences Can Help

The professionals at Epsilon Life Sciences have been at the forefront of board-level advisory services, having served as Compliance Expert under Corporate Integrity Agreements (CIAs) since this requirement was introduced. Compliance Experts assess the effectiveness and sustainability of an organization's compliance program. Our compliance program effectiveness review reports have been submitted and relied upon by boards and the OIG through the course of CIAs since 2010.

Epsilon Life Sciences has curated a proprietary set of questions from guidances, standards, and our own experience with OIG monitors, that boards should be able to answer in their oversight of the compliance program. Our reviews are designed to answer all of these questions with evidentiary support, while also addressing the 7 elements of compliance.

Epsilon Life Sciences takes a 7+ element review approach, incorporating two additional elements that are critical to compliance program maturity and effectiveness – culture and analytics. We take an immersive approach to assessing culture, leveraging pre-existing culture surveys, conducting surveys ourselves if needed, conducting culture roundtables with key stakeholders across functions (including sales, marketing, access and medical) and targeted interviews to confirm our observations. Our extensive experience with data analytics, often leveraged during investigations and litigation, supports a fit-for-purpose review of an organization's access to data, storage of data, query of data and interpretation of trends. Risk identification and risk management through data analytics is a strong signal of effectiveness, while tailored reporting for certifiers or management/ leadership supporting their oversight function reinforces the effectiveness of a compliance program.

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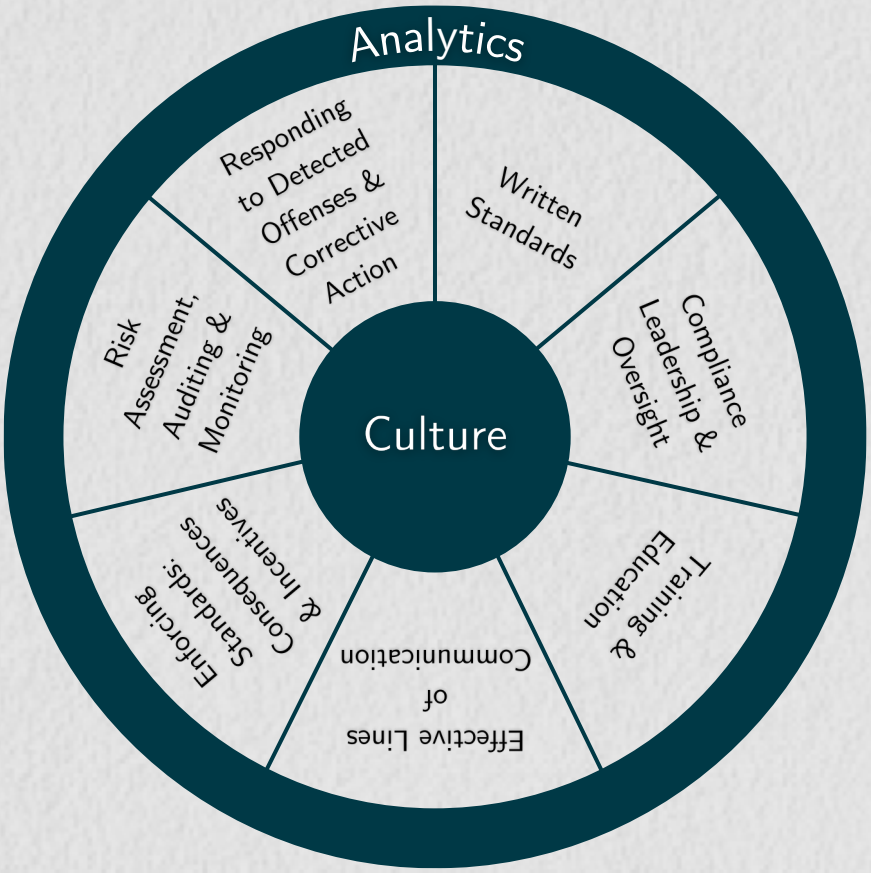

Our report structure is designed to facilitate board insights and awareness, while supporting board inquiry of the Compliance Officer, executive leadership and more broadly of the compliance program itself. The report content helps codify and retain evidence of an effective compliance program, while also guiding on continuous improvement and maturity.

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