

# Mid-Year Check-In:

Adapting the GCPG to your  
Existing Compliance Program

**SAI360**

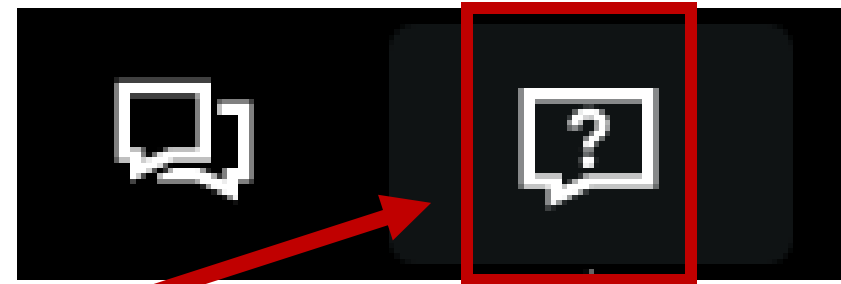


**STRATEGIC MANAGEMENT SERVICES**

# QUESTIONS OR FEEDBACK?

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# AGENDA

- Overview of the General Compliance Program Guidance
- Challenges with Implementation
- Getting Leadership Buy-In
- Questions

# WHAT IS THE GCPG?

The Office of Inspector General issued the General Compliance Program Guidance in November 2023 to serve as a reference guide for the health care compliance community at large.

The GCPG contains information about relevant laws, resources, and comments about compliance program infrastructure and risks for organizations to consider.

Voluntary and nonbinding on healthcare entities.





# INDUSTRY COMPLIANCE PROGRAM GUIDANCE (ICPGS)

- In addition, beginning in 2024, the OIG will begin publishing industry specific guidance (ICPGs) for different providers, suppliers, and other participants in the health care industry, but these will be tailored to fraud and abuse risk areas for each industry subsector.
- The ICPGs will also address compliance measures that participants can take to reduce risk.
- The OIG has indicated that managed care and nursing homes will be the first ICPGs published.

# TYPES OF OIG GUIDANCE

## Individual Compliance Program Guidance

- For different types of providers, suppliers, and other participants in health care industry subsectors or ancillary industry sectors
- Tailored to fraud and abuse risk areas for each industry subsector
- Compliance measures that participants can take to reduce risk

## General Compliance Program Guidance

- Overarching guidance document
- Seven elements of a Compliance Program
- Adaptations for small and large entities
- Other compliance considerations
- OIG process and resources

# CONSOLIDATION OF MATERIALS

- OIG intended to make the new Guidance documents very user-friendly.
- Notably, the OIG will no longer publish new or updated Guidance in the Federal Register. All current, updated, and new ICPGs will be available on the OIG's website.
- The OIG incorporates into the GCPG various other sources of information.
  - Measuring Compliance Effectiveness Toolkit
  - Practical Guidance for Health Care Boards on Compliance Oversight
  - DOJ Evaluation of Corporate Compliance Programs
  - United States Sentencing Commission, Guidelines Manual
  - A Roadmap for New Physicians Guidance

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# POLLING QUESTION 1

# OVERVIEW OF FEDERAL HEALTHCARE LAWS

- The GCPG summarizes federal laws related to healthcare fraud, including:
  - Anti-Kickback Statute
  - Physician Self-Referral Law (Stark Law)
  - False Claims Act
  - Civil Monetary Penalty Authorities
  - Exclusion Authorities
  - Criminal Health Care Fraud Statute
  - HIPAA Privacy and Security Rules

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# POLLING QUESTION 2

# CHALLENGES IN IMPLEMENTATION

WHAT ARE SOME OF THE BARRIERS TO  
INCORPORATING THE GUIDANCE INTO  
COMPLIANCE PROGRAMS?

# CHALLENGE 1

VOLUNTARY NATURE OF THE GUIDANCE



# 2023 GUIDANCE APPROACH TO VOLUNTARY NATURE

- In this instance, the OIG is consistent with its past approach: the GCPG and ICPGs are voluntary.
- The GCPG (and ICPGs) do not describe a model Compliance Program.
- The GCPG and ICPGs are intended to be used as resources by the healthcare community; they are not intended to be a one-size-fits-all, completely comprehensive or all-inclusive of compliance considerations and fraud and abuse risks for every organization.
- The OIG purposefully uses the word “should” throughout the document to demonstrate its voluntary nature.

# HOW ORGANIZATIONS CAN OVERCOME THIS CHALLENGE

- Despite voluntary nature of guidance, given the consistency with which the OIG has expressed its opinion on this topic, it is our interpretation that the OIG's guidance represents a "best practice" or "best in class" Compliance Program.
- Seriously consider whether a deviation from the OIG's guidance is necessary and can be justified.
- Look to organizations under CIAs to see what mandatory Compliance Programs look like.

# CHALLENGE 2

LACK OF EXECUTIVE SUPPORT

# 2023 GUIDANCE APPROACH TO LACK OF EXECUTIVE SUPPORT

- The OIG has long held the belief that the tone of the Compliance Program comes from the top.
- Many Compliance Programs struggle because they lack a strong “tone from the top”.
- The November 2023 Guidance sets forth specific expectations of an organization’s leadership, including the CEO and the Board.

# 2023 GUIDANCE APPROACH TO LACK OF EXECUTIVE SUPPORT

- **OIG outlines expectations of the CEO and Board members including:**
  - Leadership, including the CEO and the Board, should set the tone for the Compliance Program.
  - Regular, active and engaged participation by all members of the Compliance Committee.
  - In communications with individual compliance committee members, the Board and CEO should convey the importance of the Compliance Committee members' responsibilities and participation.
  - CEO and the Board can demonstrate a commitment to compliance with a signed introduction in the Code.
  - The Board, specifically, should take every opportunity to communicate to each of its audiences its commitment to compliance.

# 2023 GUIDANCE APPROACH TO LACK OF EXECUTIVE SUPPORT

- **OIG outlines the responsibilities of the Executive Compliance Committee to include:**
  - Analyzing legal and regulatory requirements applicable to the entity;
  - Assessing, developing, and regularly reviewing policies and procedures;
  - Monitoring and recommending internal systems and controls;
  - Assessing education and training needs and effectiveness, and regularly reviewing required training;
  - Developing a disclosure program and promoting compliance reporting;
  - Assessing effectiveness of the disclosure program and other reporting mechanisms;
  - Conducting annual risk assessments;
  - Developing the compliance workplan;
  - Evaluating the effectiveness of the compliance workplan and any action plans for risk remediation; and
  - Evaluating the effectiveness of the compliance program.

# 2023 GUIDANCE APPROACH TO LACK OF EXECUTIVE SUPPORT

- **OIG expands the responsibilities of the Executive Compliance Committee to include:**
  - Importance of the tone of the Committee being set by the CEO, and the CEO and Board members should regularly convey importance in member's Committee responsibilities and participation.
  - Regular, active, and engaged participation expected is by all members of the Committee, with enforcement suggested through each member's performance plan and compensation evaluation.
  - Composition should include relevant leaders of both operational and supporting departments who are sufficiently knowledgeable regarding their department's subject area and have the authority and ability to speak for the department they represent.

# HOW ORGANIZATIONS CAN OVERCOME THIS CHALLENGE: CEO AND BOARD

- Board members and the CEO are tasked with responsibility for the engagement of the Compliance Committee and support of the Compliance Program.
- In many ways, these concepts of supporting the Compliance Program are not new.
- However, the specific ways in which the OIG suggests implementing them may be novel to some organizations.
- Therefore, CEOs and Boards may need to be educated on these new suggested best practices.



# HOW ORGANIZATIONS CAN OVERCOME THIS CHALLENGE: COMPLIANCE COMMITTEE

Does your Executive Compliance Committee have the right membership?

Is each member of the committee sufficiently knowledgeable regarding their department's subject area?

Does each member of the committee have the authority and ability to speak for the department they represent?

- Compliance Officer
- CEO
- Revenue Cycle
- Clinical and Medical
- Finance
- Legal
- Internal Audit
- IT
- HIM
- **Quality**
- Risk Management
- Sales and Marketing
- Operational Leaders

# HOW ORGANIZATIONS CAN OVERCOME THIS CHALLENGE: COMPLIANCE COMMITTEE

- Review the Executive Compliance Committee's Charter:
  - Does your Charter accurately reflect the Committee's duties and responsibilities in light of the November 2023 guidance?
- Educate the Executive Compliance Committee on their duties and responsibilities.
  - Do your Committee members know and understand what their responsibilities are as members?

# CHALLENGE 3

REPORTING STRUCTURE AND SENIORITY  
OF COMPLIANCE OFFICER

# 2023 GUIDANCE APPROACH TO REPORTING STRUCTURE

- The OIG emphasizes that the Compliance Officer should not lead or report to Legal or Finance.
- The Compliance Officer should report directly to the CEO (with independent access to the Board) or the Board.
- 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 Compliance Program.
- The OIG emphasizes that a key indicator of the Board and senior leadership's commitment to compliance is the appointment and support of a compliance officer who has the authority, stature, access, and resources necessary to lead an effective and successful Compliance Program.

# HOW CAN ORGANIZATIONS OVERCOME THIS CHALLENGE

- This is often one of the trickiest challenges to overcome because it often is embedded in the culture of an organization.
- The OIG has been very consistent in its guidance – point to it!

# CHALLENGE 4

LIMITED RESOURCES

# 2023 GUIDANCE APPROACH TO THE LACK OF RESOURCES: SMALL ORGANIZATIONS

- Individual and Small Physician Practices can feel overwhelmed by the burden of Compliance Programs.
- For an Individual or Small Physician Practice, there are real resource constraints.

# HOW TO OVERCOME THIS CHALLENGE: SMALL ORGANIZATIONS

- Although this is a common concern for smaller organizations, the OIG addresses this concern in the 2023 Guidance.
- The GCPG offers specific suggestions on how a small organization might tailor a Compliance Program to fit the needs of a small organization (e.g. individual or small group physician practice).
- OIG provides specific suggestions to enable the small entity to gain the benefits and protection of a Compliance Program while taking into account the realistic resource constraints.



# 2023 GUIDANCE APPROACH TO THE LACK OF RESOURCES: LARGE ORGANIZATIONS

- Resources are also an issue in large organizations, due to the size and complexity of the organization and the compliance issues the program covers.
- In many instances Compliance Programs at larger organizations have difficulty securing the FTEs or budget to cover the high-risk areas implicating compliance.

# HOW TO OVERCOME THIS CHALLENGE: LARGE ORGANIZATIONS

- The Compliance Officer should rely on the Board (or Board Committee) for resources **and** report directly to the Board.
- OIG emphasizes that it is the Board's duty to consider the size and complexity of the organization in reviewing the scope and adequacy of the entity's Compliance Program.
- The Compliance Officer should organize the Compliance Department in a way that works for the Program.
- OIG suggests that the Compliance Committee of a Large Entity may require Compliance sub-committees with members possessing various expertise (e.g., policies and procedures, training and education, compliance audits, risk assessments, effective communication, etc.).

# CHALLENGE 5

INCORPORATING INCENTIVES FOR  
COMPLIANCE

# 2023 GUIDANCE APPROACH TO THE LACK OF INCENTIVES TO COMPLIANCE

- Historically, organizations have struggled to figure out how to incentivize compliance.
- The OIG has traditionally provided guidance on disciplinary standards for Compliance Programs.
- At the same time, Compliance was never intended to be punitive in nature.
- Rather, incentives should be awarded for supporting the Compliance Program.

# HOW ORGANIZATIONS CAN OVERCOME THIS CHALLENGE

- In the GCPG, the OIG considers both consequences for noncompliance as well as incentives for encouraging compliance performance and innovation.
- As a result, organizations should consider the type of behavior they want to incentivize, and the way in which they will accomplish that.

What would be an appropriate behavior to award incentives?

What would an appropriate incentive be?

# GETTING EXECUTIVE BUY-IN

HOW CAN YOU ENCOURAGE SENIOR LEADERS AND YOUR BOARD TO GET INVOLVED IN THE COMPLIANCE PROGRAM?

# GETTING BUY-IN FROM LEADERSHIP

- Reiterate the government's position.
- Encourage leadership to be involved in the implementation of the Compliance Program.
- Build relationships with senior leaders.
- Educate the Board on their oversight responsibilities of executive involvement.
- Emphasis the role of compliance in risk mitigation.

# QUESTIONS?



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