

# The New OIG General Compliance Program Guidance: A Compliance Officer's Roadmap to Protecting the Organization



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The Office of Inspector General of the U.S. Department of Health and Human Services (the OIG) is modernizing the accessibility and usability of its publicly available resources as part of its Modernization Initiative.<sup>1,2</sup> To that end, the OIG is by updating its Compliance Program Guidance (CPG) documents to ensure they are useful, informative, and “help advance the industry’s voluntary compliance efforts in preventing fraud, waste, and abuse in the health care system.”<sup>3</sup> First up – the recently revamped OIG General Compliance Program Guidance document (GCPG).<sup>4</sup> We recommend that the healthcare compliance community and other healthcare stakeholders review the GCPG carefully and, in particular, that all healthcare compliance officers ensure they use the GCPG as a roadmap for effective compliance plans going forward.

## HISTORY OF THE CPG DOCUMENTS

The OIG has been releasing *voluntary, nonbinding* CPG documents since 1998 “to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements.”<sup>5</sup> The GCPG discusses general compliance risks and considerations.<sup>6</sup> Next, the OIG will begin publishing industry-specific CPGs to update prior CPGs that provide guidance for specific providers such as hospitals, clinical laboratories, hospices, Medicare Advantage (formerly known as Medicare + Choice) organizations, and nursing facilities.<sup>7</sup> The OIG anticipates updating the existing CPGs for Medicare Advantage organizations and nursing facilities first, followed by updating the CPGs addressing hospitals and clinical laboratories.<sup>8</sup> While previous CPGs were released in the Federal Register, going forward the OIG will publish them directly to its website.<sup>9</sup> As new CPGs are released, prior CPGs will be archived but will remain available as resources on the OIG’s website.<sup>10,11</sup>

Although the CPG documents are *voluntary*, federal law requires that many organizations, such as Medicare Advantage Organizations<sup>12</sup> and Medicare Part D Prescription Drug Plans,<sup>13</sup> have compliance programs in place. Moreover, even when an organization is not legally required to have a compliance program, the fact that an organization has an effective compliance program in place can serve as a mitigating factor when federal agencies, such as the OIG, determine the level of punishment that a culpable organization will face when they are found to have violated fraud and abuse laws. According to the U.S. Department of Justice (DOJ), taking proactive compliance steps “may not only be rewarded in connection with the form of any resolution or prosecution (such as through remediation credit or a lower applicable fine range under the Sentencing Guidelines), but more importantly, may avert problems down the line.”<sup>14</sup>

## THE GCPG – OVERVIEW

A summary of the information discussed in the GCPG is provided below.<sup>15</sup>

■ **Overview of Relevant Laws.** These federal laws<sup>16</sup> include, but are not limited to, the Anti-Kickback Statute, the Physician Self-Referral Law, the False Claims Act, and HIPAA Privacy and Security Rules. Useful tips are provided, such as those listed below, which are also discussed in this article.

- Inquiries to ask when identifying problematic arrangements under the Anti-Kickback Statute.
- Steps to take to reduce or eliminate the risk of Anti-Kickback Statute violations.
- What to do when an organization discovers that it has employed or contracted with an individual or entity that is excluded from participation in federal healthcare programs.

■ **The Seven Elements of an Effective Compliance Program.** Each element is

discussed, along with useful tips to aid in ensuring that a successful compliance program is put in place:

- *Element 1 – Written Policies and Procedures.* Compliance policies and procedures should, at the very least, encompass the implementation and operation of the entity's compliance program and processes to reduce risks caused by noncompliance with the applicable laws. A Code of Conduct is also a necessary element for a compliance program.
- *Element 2 – Compliance Leadership and Oversight.* It is important to have a designated compliance officer authorized to oversee and monitor the operation of the compliance program.
- *Element 3 – Training and Education.* The compliance officer must ensure the organization's staff is trained on the compliance program.
- *Element 4 – Effective Lines of Communication with the Compliance Officer and Disclosure Program.* It is essential that staff know how to reach the compliance officer directly and that they are encouraged to bring compliance questions and concerns to the compliance officer.
- *Element 5 – Enforcing Standards: Consequences and Incentives.* It is important to establish appropriate consequences for instances of noncompliance, in addition to incentives for compliance.
- *Element 6 – Risk Assessment, Auditing, and Monitoring.* A risk assessment provides a process to identify, analyze, and respond to risk. Audits are then conducted based on risks identified by the risks assessments. Routine monitoring is needed to review ongoing risks and the effectiveness of controls and mediation plans that have been put in place.

- *Element 7 – Responding to Detected Offenses and Developing Corrective Action Initiatives.* When offenses are detected it is important to develop corrective action plans, which may include reporting or self-disclosing to the appropriate agencies, refunding any overpayments, enforcing disciplinary policies and procedures, and making any policy changes necessary to prevent recurrences of the misconduct.
- **Compliance Program Adaptations for Small and Large Entities.** The OIG acknowledges that implementation of an effective compliance program should be customized to the size of the organization. The GCPG therefore provides guidance regarding how small entities can implement a compliance program that satisfies the seven elements, even with limited resources, and how larger entities can ensure the compliance needs of larger organizations are met. For example, the OIG recommends that small entities dedicate the necessary time and resources for each compliance risk assessment but avoid making the process too complicated or resource intensive.
- **Other Compliance Considerations.** The GCPG also discusses generally applicable risk areas that should be considered when working towards eliminating potential fraud and abuse risks. The following areas should not be considered as wholly separate and distinct from compliance: (1) quality and patient safety, (2) the growing prominence of private equity in healthcare, and (3) how to appropriately track financial arrangements, including those with referral sources that can implicate the Anti-Kickback Statute and other fraud and abuse laws. For example, the OIG and the DOJ have brought False Claims Act cases based on materially substandard care.
- **OIG Resources and Processes.** The GCPG discusses various healthcare resources, such as the OIG's Compliance section of

its website,<sup>17</sup> updated Frequently Asked Questions,<sup>18</sup> and the ability to subscribe to the OIG's "What's New" Newsletter to receive notifications regarding new reports, enforcement actions, and more.<sup>19</sup> The OIG also suggests using Corporate Integrity Agreements (CIAs) that the OIG has entered into with healthcare providers and other entities as a resource when an organization reviews its compliance program structure and operations.<sup>20</sup> The OIG's CIA webpage includes an abundance of resources, such as recent and closed CIAs and CIA Frequently Asked Questions.

### **THE GCPG – A ROADMAP FOR COMPLIANCE OFFICERS**

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Compliance officers will find the revamped GCPG particularly helpful. It goes a step further than prior CGPs by offering useful tools and tips regarding how to mitigate risks and maintain compliance with federal healthcare program requirements. Some recommendations include:<sup>21</sup>

- **Review Policies and Procedures Annually.** Review compliance policies and procedures at least annually to ensure they reflect any modifications to applicable statutes, regulations, and federal healthcare program requirements.
- **Be an Effective Compliance Committee Chair.** Follow the GCPG's guidance regarding how to appropriately chair the Compliance Committee, which, for example, includes providing training to new committee members regarding their duties and responsibilities.
- **Be an Effective Member of Senior Leadership.** It is important for compliance officers to be included as members of Senior Leadership, the group of leaders who report directly to the executive leading the entity, and to be treated as an equal among these leaders. For example, the GCPG specifically provides that the compliance officer should "have sufficient stature within the entity to interact as an equal of other senior leaders

of the entity.” The GCPG further provides that some ways to ensure that the compliance officer has the appropriate authority within the organization is for them to be provided with sufficient funding, resources, and staff to enable them to do their duties appropriately. Another suggestion that has been made is to create a cohesive relationship between the legal and compliance departments, because by “embracing strategies that promote collaboration and understanding, healthcare entities can enhance their capacity to manage risk, uphold ethical standards, and achieve their strategic objectives, securing their position as leaders committed to excellence in healthcare delivery.”<sup>22</sup>

- **Access to the Board.** Compliance officers should always have “direct and uninhibited” access to the Board and meet with the Board on a regular basis, but no less than quarterly. The GCPG suggests using the “Practical Guidance for Health Care Governing Board on Compliance Oversight”<sup>23</sup> to determine and evaluate how the Board can effectively perform its obligations to the organization. It is also recommended that specific training be prepared and provided to the Board that addresses areas such as the risks faced by the organization and how the Board can provide oversight.
- **Offer Additional Compliance Education Opportunities.** Compliance Committee members and entity leaders should be directed to have a standing compliance item on the agendas of the meetings they usually attend (e.g., executive leadership meetings and medical staff meetings). This will give them the opportunity to deliver compliance trainings and share other relevant compliance information during those meetings.
- **Do Not Deter Reporting of Compliance Concerns.** Ensure individuals are not deterred from reporting compliance concerns (e.g., personnel should not be required to bring compliance concerns

to their manager or supervisor before contacting the compliance officer).

- **Maintain Responsibility for Investigations.** Remain involved in all communications of healthcare compliance investigations when counsel takes the lead.
- **Be Independent from Legal or Financial Functions.** Although it is important to remain involved in healthcare compliance investigations, do not provide legal or financial advice to the organization or supervise anyone who does.
- **Review Medical Necessity.** “[E]nsure that any claim reviews and audits include a review of the medical necessity of the item or service by an appropriately credentialed clinician.” Failure to take this crucial step means that important compliance issues likely go undetected.
- **Identify Problematic Arrangements.** When attempting to identify problematic arrangements, review the inquiries provided in the GCPG. Determine which follow-up steps may be necessary to reduce or eliminate the risk of an Anti-Kickback Statute violation. We recommend compliance officers create checklists from the information provided in the GCPG to help them identify problematic arrangements and then determine which follow-up steps to take. For example, the GCPG includes some key questions that should be asked when determining whether an arrangement violates the Anti-Kickback Statute, such as, “Are the items and services actually needed and rendered, commercially reasonable, and necessary to achieve a legitimate business purpose?” and “Does the arrangement or practice raise concerns related to steering patients or health care entities to a particular item or service, or steering to a particular health care entity to provide, supply, or furnish items or services?”
- **Review Compliance Program Effectiveness.** If audit results continue to not identify any risks to the organization, consider conducting a compliance



program effectiveness review to determine why risks are not being identified and/or reported. The GCPG suggests using the OIG's/Health Care Compliance Association (HCCA) resource, "Measuring Compliance Program Effectiveness: A Resource Guide."<sup>24</sup> This resource provides program metrics to review when evaluating a compliance program. For example, the compliance officer can measure how often staff open particular compliance policies to determine if the policies are being utilized.

■ **Conduct Root Cause Analyses.** During compliance investigations, gather information to help determine the root causes of the conduct so that the organization is able to make any required changes to prevent future recurrences of illegal or inappropriate conduct. The Joint Commission provides a "Framework for Root Cause Analysis and Corrective Actions"<sup>25</sup> that may be useful when determining the root causes of the improper conduct. The framework document provides analysis questions that should be asked when determining why the event occurred and how to prevent future events. For example, one question that should be asked is whether staff was trained regarding appropriate conduct.

■ **Have Sufficient Resources to Perform Essential Duties.** If serving as the compliance officer and privacy officer, ensure there are sufficient staff and resources to perform the additional duties associated with serving in both roles.

## GET STARTED

Now is the time for compliance officers to ensure they have effective compliance programs in place. A thorough review of the GCPG is a great starting place. As discussed above, although the GCPG guidance is voluntary, adhering to its recommendations could prevent future violations and even reduce any penalties that could be imposed

in the event of sanctions due to violations of the fraud and abuse laws.

## Endnotes

1. 86 Fed. Reg. 53072 (Sept. 24, 2021), available at: <https://www.govinfo.gov/content/pkg/FR-2021-09-24/pdf/2021-20558.pdf>.
2. U.S. Department of Health and Human Services, Office of Inspector General, General Compliance Program Guidance, November 2023, available at: <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>.
3. 88 Fed. Reg. 25000 (Apr. 25, 2023), available at: <https://www.govinfo.gov/content/pkg/FR-2023-04-25/pdf/2023-08326.pdf>.
4. U.S. Department of Health and Human Services, Office of Inspector General, General Compliance Program Guidance, November 2023, available at: <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>.
5. 88 Fed. Reg. 25000 (Apr. 25, 2023), available at: <https://www.govinfo.gov/content/pkg/FR-2023-04-25/pdf/2023-08326.pdf>.
6. *Id.*
7. *Id.*
8. *Id.* See U.S. Department of Health and Human Services, Office of Inspector General, Compliance Guidance, available at <https://oig.hhs.gov/compliance/compliance-guidance/>.
9. *Id.*
10. *Id.*
11. U.S. Department of Health and Human Services, Office of Inspector General, Compliance Guidance, available at: <https://oig.hhs.gov/compliance/compliance-guidance/>.
12. 42 C.F.R. § 422.503(b)(4)(vi).
13. 42 C.F.R. § 423.504(b)(4)(vi).
14. U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs, Updated March 2023, pg. 15, available at: <https://www.justice.gov/criminal-fraud/page/file/937501/download>.
15. U.S. Department of Health and Human Services, Office of Inspector General, General Compliance Program Guidance, November 2023, available at: <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>.
16. For purposes of this article, any references to laws are referring to federal laws. We do not discuss state-specific laws in this article, although compliance officers should also consider applicable state laws when implementing an effective compliance program.
17. U.S. Department of Health and Human Services, Office of Inspector General, Compliance, available at: <https://oig.hhs.gov/compliance/>.
18. U.S. Department of Health and Human Services, Office of Inspector General, Frequently Asked Questions, available at: <https://oig.hhs.gov/faqs/>.

19. U.S. Department of Health and Human Services, Office of Inspector General, HHS-OIG Newsletter Subscriptions, available at: <https://cloud.connect.hhs.gov/OIG/>.
20. U.S. Department of Health and Human Services, Office of Inspector General, Corporate Integrity Agreement, available at: <https://www.oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp>.
21. U.S. Department of Health and Human Services, Office of Inspector General, General Compliance Program Guidance, November 2023, available at: <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>.
22. Journal for Health Care Compliance, Volume 26, Number 2, March – April 2024, Frankly Speaking: Understanding the Tension Between In-house Counsel and Compliance Officers in Healthcare Organizations, by Frank Sheeder.
23. Office of Inspector General, U.S. Department of Health and Human Services, Association of Healthcare Internal Auditors, American Health Lawyers Association, Health Care Compliance Association, Practical Guidance for Health Care Governing Boards on Compliance Oversight, April 20, 2015, available at: <https://oig.hhs.gov/documents/root/162/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>.
24. Health Care Compliance Association and Office of Inspector General, Measuring Compliance Program Effectiveness: A Resource Guide, January 17, 2017, available at: <https://oig.hhs.gov/documents/tool-kits/928/HCCA-OIG-Resource-Guide.pdf>.
25. Joint Commission, Framework for Root Cause Analysis and Corrective Actions, available at: [https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/rca\\_framework\\_101017.pdf](https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/rca_framework_101017.pdf).

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