

### **Alert for Healthcare Providers: Keeping up with Compliance – Additional Guidance from the OIG**

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In November 2023, the Office of Inspector General (OIG) issued a new General Compliance Program Guide (GCPG) which seeks to clarify its existing voluntary compliance program by updating information and making that information more easily accessible to health care entities. This represents the OIG's first update to its existing 2008 general guidance.

The new GCPG discusses the well-established "Seven Elements" of an effective compliance program, which include:

- (1) Written Policies and Procedures;
- (2) Compliance Leadership and Oversight;
- (3) Training and Education;
- (4) Effective Lines of Communication with the Compliance Officer and Disclosure Program;
- (5) Enforcing Standards: Consequences and Incentives;
- (6) Risk Assessment, Auditing, and Monitoring; and
- (7) Responding to Detected Offenses and Developing Corrective Action Initiatives.

Although the seven elements have not changed, the updated GCPG offers new insight that should assist health care entities in implementing applicable compliance measures. **The OIG indicated that it will continuously amend the elements and the general guidelines of the GCPG to remain in compliance with changes in best practice and law, so it is imperative that entities who are self-reporting remain up to date.**

In addition to the core elements and federal law sections, the GCPC also provides guidance related to quality and patient safety, new entrants in the health care industry, financial incentives, and tracking of financial arrangements. The financial arrangement guidance is particularly pertinent for all entities in the health care space to ensure compliance with fraud and abuse laws and regulations.

Entities should leverage Section II of the GCPG to better understand applicable federal law implications, including regarding the Federal Anti-Kickback Statute, Physician Self-Referral Law (Stark Law), and the False Claims Act. The GCPG provides insights into key questions that health care entities should ask to ensure they are aligned with federal regulations, offers examples of problematic arrangements and activities, and outlines interventions that can be completed when a problem is identified. The GCPG provides a solid framework for health care entities to rely on to review and assess their adherence to federal fraud and abuse laws, but it does not cover state fraud and abuse law. Therefore, individuals relying on this guidance should still consult with attorneys to ensure their compliance programs incorporate and comply with all applicable laws.

To ease the transition for all entities, the OIG included in the new GCPG various processes for both small and large health care organizations to account for differences in resources and staffing. The additional guidance for small health care entities should be particularly useful so that those with less staffing or resources can still leverage this guidance.

Earlier this year, OIG announced its intention to publish “industry segment-specific compliance program guides” (ICPGs). The OIG has indicated that these ICPGs will focus on fraud and abuse risk areas and will address compliance measures within each specific health care industry. The OIG has communicated that the first two ICPGs will cover Medicare Advantage and nursing facilities and are expected to be published this year. Next, the OIG plans to address hospitals and clinical laboratories.

The new GCPG is not the only resource available; however, providers should become familiar with its recommendations and work with their staff to implement as many strategies and procedures as possible to best avoid potential issues related to fraud and abuse in their practices. The OIG encourages participation of health care providers and asks that any feedback or input from the health care community to be sent to [Compliance@oig.hhs.gov](mailto:Compliance@oig.hhs.gov).

*Please contact one of the authors or any member of Bodman’s [Health Care Practice Group](#) to discuss the new General Compliance Program Guide or any other legal issue facing your organization. Bodman cannot respond to your questions or receive information from you without first clearing potential conflicts with other clients. Thank you for your patience and understanding.*

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