

BRG CORPORATE INTEGRITY AGREEMENT ADVISORY AND SUPPORT SERVICES



Overview

The US Department of Health and Human Services Office of the Inspector General (OIG) has primary oversight responsibility of, and significant enforcement authority within, government healthcare programs including Medicare and Medicaid. OIG also periodically reports to Congress on its initiatives and progress. OIG's enforcement authority includes the ability to exclude organizations from participation in government healthcare programs entirely. Criminal violations result in mandatory exclusion from government healthcare programs. Once excluded, an entity must reapply to participate in federal healthcare programs, and many commercial insurers refuse to interact with excluded providers. Civil violations normally are investigated and resolved under the federal False Claims Act (FCA), Anti-Kickback Statute (AKS), and/or other state and federal healthcare fraud, waste, and abuse (FWA) laws. OIG is given more leniency in exclusion for civil violations, with permissive authority to exclude providers if certain conditions are met.

OIG, the US Department of Justice (DOJ), and state Medicaid Fraud Control Units (MFCUs) have demonstrated remarkable creativity in investigating and resolving civil healthcare fraud allegations. From health plans and managed care payors to life sciences firms to healthcare organizations (HCOs) and health information technology (HIT) vendors, no segment of the healthcare industry is immune from enforcement action.

When OIG resolves civil healthcare fraud allegations, it typically requires the target organization to enter into a corporate integrity agreement (CIA) to avoid exclusion from participation in federal healthcare programs. A CIA is a detailed operational agreement. CIAs generally last five years, and OIG tailors the obligations of each CIA to address the problematic conduct identified.

CIAs establish comprehensive obligations regarding:

- Compliance program design and operational effectiveness
- Amplified transparency
- Periodic reports and certifications by the organization
- Independent reviews and assessments to verify compliance with CIA obligations

BRG's CIA Advisory and Support Services Team is highly experienced in operationalizing CIA obligations while preserving significant bandwidth for your team to work on higher-value matters and for your client's in-house legal and compliance personnel to perform their usual day-to-day responsibilities. More important, we consistently exceed OIG's expectations with best-in-class healthcare data analysis and ethically informed healthcare compliance and governance effectiveness guidance.



Compliance Program Design and Operational Effectiveness

OIG mandates that the organization establish or upgrade a compliance and ethics program. This typically includes operational requirements such as department leadership and composition, executive communication lines, and hotline reporting mechanisms. OIG also expects periodic comprehensive reports on the progress of implementing the elements it requires.

Over the past ten to fifteen years, both OIG and DOJ have focused their attention on the critical role that governance and oversight play in compliance program effectiveness. They stress that “tone at the top” and leading by example are two fundamental concepts underpinning the effectiveness of every compliance program. Consequently, they expect, at minimum, that healthcare governing bodies and senior management are educated on an organization’s regulatory compliance risks and have developed robust communication channels to discuss and remediate compliance issues.

Implementing these operational, cultural, and governance enhancements involves significant human capital and financial resources beyond those already needed for the organization to function.

Amplified Transparency

OIG also requires that organizations establish processes for identifying, monitoring, and reporting designated “reportable events” to OIG. “Reportable events” vary by CIA but usually include suspected overpayments, potential legal violations, and pending changes to executive or governing body personnel affecting oversight of the organization’s compliance and ethics program.

These amplified transparency obligations require enhanced monitoring and auditing capabilities to identify reportable events. The reports themselves can be tedious, including a description of the event and how it was identified and mitigated. Experience completing these reports is critical to meet this obligation efficiently while meeting OIG’s exacting standards.

Periodic Reports and Certifications by the Organization

OIG requires the organization’s management to file periodic reports and certifications related to implementing the CIA obligations. These periodic reports are usually required at initial implementation and annually thereafter. As with the amplified transparency obligations, experience successfully completing OIG’s periodic reports is essential to preserve enterprise efficiency and navigate a CIA effectively.

Independent Reviews and Assessments

OIG expects organizations to retain independent data analytics and claims-testing experts to review their claims submissions to federal healthcare programs for compliance with regulations and program requirements. These reviews require demanding reports to OIG and certification with Generally Accepted Government Audit Standards.

In addition, OIG requires the organization’s governing body to retain independent compliance experts to advise on fiduciary duties and oversight responsibilities. This usually entails compliance program effectiveness assessments with improvement recommendations, and training sessions on regulatory standards and key enforcement initiatives.

Services Offered

BRG professionals have extensive experience navigating the complexities and challenges of complying with CIA obligations. We understand the OIG's expectations and know how to meet their general standards. We also understand that CIAs include client-specific obligations. BRG can develop a customized strategy to address these specific CIA obligations.

BRG CIA Advisory and Support Services include:

ADVISOR TO THE COMPANY

The advisor to the company does not require independence. Our team of experienced compliance professionals collaborate effectively with outside counsel to advise and assist compliance and legal departments in implementing their CIA obligations, including preparing required implementation and periodic reports.

BOARD'S INDEPENDENT COMPLIANCE EXPERT

The board's compliance expert is required to be independent from the company. Our seasoned governance advisors ensure the board of directors receives appropriate education on its fiduciary duties and oversight responsibilities regarding the compliance and ethics program. Our advisors also perform periodic comprehensive compliance program reviews and draft corresponding reports that reflect an understanding of the OIG's extensive guidance regarding program effectiveness.

INDEPENDENT REVIEW ORGANIZATION (IRO) AND/OR QUALITY REVIEW ORGANIZATION (QRO)

An IRO or QRO also must be independent. Our data analytics and auditing capabilities position us to efficiently perform arrangements, systems, claims, transactional, and unallowable costs reviews and produce corresponding reports as required by each CIA's carefully crafted obligations.



About BRG

Berkeley Research Group (BRG) is a global consulting firm that helps leading organizations advance in three key areas: disputes and investigations, corporate finance, and performance improvement and advisory. Headquartered in California with offices around the world, we are an integrated group of experts, industry leaders, academics, data scientists, and professionals working beyond borders and disciplines. We harness our collective expertise to deliver the inspired insights and practical strategies our clients need to stay ahead of what's next.

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