

## Preparing for a Corporate Integrity Agreement

[Richard P. Kusserow](#) | February 2023

### Key Points:

- **10 Tips to consider when negotiating a CIA**
- **Frequently asked CIA questions**

At any given time, the OIG actively monitors over 300 Corporate Integrity Agreements (CIAs), with more added monthly. CIAs normally follow from civil settlements with the DOJ. An organization consents to defined obligations in exchange for the OIG not seeking an exclusion from participation in Federal health care programs. [Terms and conditions](#), along with engaging [Independent Review Organizations](#) (IROs), are designed to ensure future compliance with applicable laws and regulations. Counsel to the Inspector General negotiates and monitors these agreements that are for usually for a period of five years. The OIG attorney assigned to monitor compliance with the terms of the CIA will be different from the attorney who negotiated it. The following are tips to consider when negotiating a CIA with the OIG:

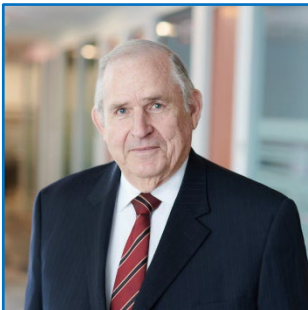
1. Be prepared to provide evidence to the OIG as to why a CIA may not be needed because (a) the misconduct is being addressed by the current compliance program and internal controls; and (b) current safeguards ensure future integrity in Federal health care programs.
2. At first indication of a DOJ or OIG investigation, the Compliance Officer should engage outside, independent experts to conduct an evaluation of the compliance program and take immediate steps to implement any recommendations addressing program weaknesses. The OIG and DOJ view independent reviews as far more credible than any internally generated information. As such, the report and subsequent actions would be viewed positively and may result in some mitigation by the authorities.
3. Engage attorneys with experience negotiating settlements with the OIG and have understanding of business operations to work out terms. In too many cases, attorneys lacking such background have conceded to terms and conditions that proved to be far more expensive in terms of time and effort when it came time to meet them.

4. The Compliance Officer should actively and visibly participate in the negotiations of a CIA. This is something that the OIG has actively promoted but is also important in understanding the implication of proposed terms being considered in the time, effort, and cost for compliance.
5. Work to educate the OIG attorney in the understanding and appreciation of business operations. Misunderstandings here could aggravate the burden of any CIA-mandated terms. The attorney handling the settlement process may lack understanding of the health care operations and fail to appreciate the significance of what may be asked for in the CIA.
6. Consider having available [Subject Matter Experts](#) to help ensure (a) CIA terms and conditions are clear and unambiguous, (b) the scope of the IRO is well defined, and (c) a complete understanding of the implications of the commitments under the CIA
7. Understand that the OIG attorneys who may have worked with the DOJ on their process are different from those who develop CIAs. They are unlikely to have any knowledge beyond the court decision or settlement terms with DOJ and are not interested in arguing any terms with a legal counsel.
8. Once there is a settlement with the DOJ, legal counsel must be discouraged from trying to re-litigate or argue issues settled in that agreement with the OIG attorneys. The OIG will always reject any such discussion and, by attempting to do so, will serve only to aggravate matters and sharpen the terms of the CIA. It is far better to make a fresh start with a commitment to put the problem behavior in the past and move forward to reinstate their good standing.
9. Leave no issue for clarification in the CIA once it is signed. The time to identify potential problems in a CIA is before it is signed. To avoid future problems and costs in negotiating [CIA terms](#), conditions, and requirements, it is important to ensure:
  - Scope and breadth of the CIA are clearly outlined and defined
  - Clear understanding of what is expected to evidence compliance with CIA terms
  - All terms and conditions are studied and understood
  - All “covered persons and “relevant covered persons” are defined
  - Clear understanding of applicable government regulations and manual provisions
  - What exactly the OIG considers an “error” and acceptable “error rate”
  - How “substantial” overpayments are defined
  - Understanding the full scope of work to be conducted by an [IRO](#)
  - Organization is ready, willing, and able to comply with everything being proposed

- 10.** Give consideration to having a “mock” review before the IRO begins work. This will better prepare the organization to meet the IRO review. If the IRO reports can evidence full compliance with the terms of the CIA in the first years, the organization is in a better position to make a case later for a reduction of the length of the CIA.

For answers to compliance FAQs, see <https://www.compliance.com/faqs/>

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### **About the Author**

Richard P. Kusserow established Strategic Management Services, LLC, after retiring from being the DHHS Inspector General, and has assisted over 2,000 health care organizations and entities in developing, implementing and assessing compliance programs.