

2012 OIG Roundtables on Corporate Integrity Agreements

In February and August 2012, the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) held roundtable discussions with compliance representatives from 32 companies that had entered into Corporate Integrity Agreements (“CIAs”) with the OIG since 2009. The discussions were designed to provide feedback to the OIG on practical implementation issues associated with CIA requirements. Both roundtables addressed challenges with CIA implementation and offered suggestions for improvement. The OIG summarized the discussions in two summary reports: [*Report from February 23, 2012, Pharmaceutical Compliance Roundtable*](#), issued on March 26, 2012, and [*Focus on Compliance: The Next Generation of Corporate Integrity Agreements*](#), issued on October 9, 2012. It also noted areas where companies expressed an intention to continue CIA-based practices even after their CIA expires. These references may be seen as an attempt by OIG to mold best practices for compliance programs industrywide.

Key points from the reports are noted below.

CIA Training Requirements. CIAs require general training on CIAs and compliance programs for all covered persons, and specific training on defined subject areas. Roundtable participants noted difficulty in determining which employees, vendors and contractors are subject to training requirements under CIA definitions. Participants reported that this confusion led companies to interpret the definition of relevant covered person very broadly, such that training was provided to categories of persons to whom the training was not relevant or meaningful. Participants recommended a more tailored definition of covered and relevant covered persons. Participants also voiced the need for guidance in providing training for contractors that provide services to more than one company.

Participants also noted that the 160-hour threshold used to identify part-time persons for purposes of the CIA’s training exception proved difficult to apply in practice due to burdensome time tracking. Some participants advocated for an exception to the covered persons definition that focused more broadly on an individual’s role, responsibilities and status as a full-time or part-time employee rather than on an hourly threshold.

Some participants commented that the CIA annual training requirements are too prescriptive with respect to content, hours and completion period. Participants made the following recommendations:

- Eliminating the minimum training hours requirement in favor of focusing training on specific employees and general efficacy of training;
- Eliminating the short time frame for implementation of CIA requirements, which would permit the use of more company-specific or risk-specific policies and training materials;
- Eliminating the requirement to track training completion for all employees, which would permit companies to use more effective multiple short training sessions; and
- Modifying the training requirements to allow for more flexible training plans, including training tailored to identified risk areas, satisfaction of general training requirements through competency testing, and the use of certifications of training attendance and completion.

Roundtable participants indicated that their companies would continue training efforts after termination of the CIA, but would make training more flexible and individually tailored to their companies’ needs. In

addition, participants noted that future compliance training would emphasize the quality of the training over the number of hours of training provided.

Role of the Compliance Officer. CIAs require that each company appoint a compliance officer who is a member of senior management to be responsible for developing and implementing policies, procedures and practices to ensure compliance. Echoing longstanding OIG guidance, roundtable participants stated that they found this structure beneficial, and emphasized the importance of having the compliance officer report directly to the board of directors rather than the general counsel or the chief financial officer.

Role of the Board of Directors. CIAs generally require that the board of directors receive training; receive reports from the compliance officer; and adopt an annual resolution certifying to the board's oversight of the compliance program. Roundtable participants reported that it was critical for boards of directors to be involved in compliance oversight and that the integration of compliance efforts into business activities enhanced the effectiveness of the compliance program. Additionally, roundtable participants noted that an engaged board of directors assists in the allocation of resources to the compliance program and provides additional motivation for the company. Some participants suggested that boards of directors be provided with additional training and tools to help assess risk, and requested that OIG publish more board of director guidance on the OIG web site.

Roundtable participants predicted that the board of directors would remain engaged in the compliance program even after the CIA's term ended, and agreed that such involvement would be vital to the compliance program's success.

Independent Review Organizations. Most CIAs require that companies retain IROs to review arrangements with referral sources, claims, or similar transactions. Roundtable participants reported that the costs of hiring an IRO, particularly in the first year of the CIA, can be high, and noted that companies devote significant compliance resources to educating the IROs about company-specific systems and processes. Some participants suggested that a better use of resources may be to permit the company to conduct internal audits subject to verification by the IRO. Other participants suggested that IRO review of "big picture" compliance items would be more useful than multiple transaction reviews.

Roundtable participants indicated that after the termination of the CIA, their companies would rely on external parties such as IROs to conduct reviews, but would do so on a limited basis. Some participants stated that internal audits are equally beneficial, and would be continued with some external verification, either using the current IRO or another third party.

Flexibility in Monitoring. Many CIAs require companies to monitor particular types of activities, which generally reflect areas of noncompliance that led to the CIA originally. Roundtable participants reported that these monitoring obligations typically are focused on past conduct, and, because roles evolve over time, the obligations become stale. Participants requested that the OIG permit companies greater flexibility in self-monitoring, particularly in the later years of a CIA.

The reports provide useful guidance as to areas in which the OIG may be open to change. They also suggest areas in which OIG, by agreement, may be willing to modify current CIA requirements. Finally, the OIG's commentary regarding post-CIA compliance provides helpful insight as to the OIG's expectations for compliance program best practices.