

Frequently Asked Questions Related to IRO Independence

Introduction

As a result of the Sarbanes-Oxley Act and an increased focus on issues relating to auditor independence, the OIG has been receiving a number of inquiries from individuals and entities subject to Corporate Integrity Agreements (CIAs) regarding circumstances that might affect the independence of an Independent Review Organization (IRO) that performs CIA reviews (*i.e.*, claims reviews, cost report reviews, systems reviews, drug price reporting reviews, etc.) for the individual/entity. In response to these inquiries, the OIG has reviewed its prior guidance regarding the factors that should be considered when assessing an IRO's independence and has determined that additional guidance in this area is appropriate.

The following is a brief summary of the OIG's views on the relevant principles that should be used to assess the independence of an IRO that performs CIA reviews, followed by a series of responses to specific questions received by the OIG regarding independence.

Summary of OIG's Views on Applicable Independence Standards

The OIG has determined that it is appropriate to adopt the standards for auditor independence set forth in the General Accounting Office (GAO), *Government Auditing Standards (2003 Revision)* (referred to as the "Yellow Book"). Under these standards, CIA reviews would be considered performance audits¹ and IROs would be subject to the independence standards set forth in the Yellow Book that relate to performance audits.² These independence standards require, among other things, that the audit organization have an internal quality control system to help determine whether auditors have any personal impairments (*e.g.*, family relationships, financial interest, etc.) to independence that could affect their impartiality or appearance of impartiality.³

In addition, under the Yellow Book standards, IROs that perform CIA reviews and also provide other CIA-related services would be subject to the independence standards that apply when an audit organization agrees to perform nonaudit services for the same client.⁴ When assessing independence, the two overarching principles that must be considered are that: (i) audit organizations should not perform management functions or make management decisions; and (ii) audit organizations should not audit their own work

¹ See GAO Yellow Book, Subchapters 2.09 – 2.13

² See GAO Yellow Book, Subchapters 3.01 – 3.18

³ See GAO Yellow Book, Subchapter 3.07

⁴ See GAO Yellow Book, Subchapters 3.13 – 3.16

or provide nonaudit services in situations where the nonaudit services are significant/material to the subject matter of the audits.⁵

Under the standards set forth in the Yellow Book, the analysis of whether a specific CIA-related service provided by an IRO will impact the IRO's independence for purposes of conducting the provider's CIA reviews does not change based on whether the same or different individuals from the IRO are performing the CIA-related services and the CIA reviews. In other words, if the IRO's performance of a CIA-related service potentially impacts the IRO's independence, the fact that separate individuals or groups within the IRO organization are responsible for performing the CIA-related service and the CIA reviews does not eliminate or reduce the independence concerns.⁶

Frequently-Asked Questions

The following is a series of questions that include scenarios posed to the OIG regarding IRO independence.

Question: If the IRO provides financial audits, bookkeeping, or tax services for the provider, can the IRO also conduct the CIA reviews (i.e., claims reviews, cost report reviews, systems reviews, drug price reporting reviews, etc.)?

Financial audits: The fact that an entity is a provider's financial auditor likely would not preclude that entity from acting as an IRO to conduct the CIA reviews for two reasons. First, a financial audit does not involve the audit organization performing management functions or making management decisions. Second, the CIA reviews are typically unrelated to the preparation of financial statements so that the IRO would not be in a position of auditing its own work, and the financial audit would not be significant/material to the subject of the CIA reviews.

Bookkeeping and tax services: The determination of whether an entity that provides bookkeeping and tax services for a provider could also serve as the provider's IRO depends on the type of bookkeeping and tax services at issue. To the extent that the services are purely technical in nature, do not involve the performance of management functions, and do not relate to the subject matter of the CIA review, it likely would be permissible for the entity performing such services to also act as the IRO. For example, if an entity provides payroll services for the provider, it likely would be permissible for that entity to act as the IRO for the CIA reviews.

⁵ Id.

⁶ See GAO Yellow Book, Subchapter 3.17

Question: If a provider uses software (e.g., billing, coding, training, etc.) developed by the IRO, can the IRO conduct the CIA reviews?

To the extent that a provider uses software that was developed by an entity and the software relates to the subject matter of the CIA review at issue, that entity likely would be precluded from acting as the IRO for the provider, because this situation would put the IRO in a position of auditing its own work. For example, if an IRO created a billing/coding or training program for the billing and/or coding personnel at a provider, the IRO likely would be precluded from conducting the CIA claims review. However, if the provider has made substantive changes to the software program (e.g., billing edits, etc.) in areas material to the subject matter of the CIA review, the entity that developed the software may be able to act as the IRO.

Question: Can the IRO provide training and conduct the CIA reviews?

The concept of training can be divided into the following categories: (1) CIA general training; (2) CIA specific training; and (3) provider staff attending training seminars presented by IRO personnel.

CIA General Training

General training usually addresses the requirements of the CIA and introduces employees to the provider's overall compliance program. If the content of the general training relates to the broad outlines of the provider's compliance program and does not focus on specific coding and billing policies (e.g., does not serve as a 'how-to' course for billing) or on any other policies and procedures that may be significant/material to the subject matter of the CIA reviews, allowing the IRO to perform this type of training likely would not impact the IRO's independence for purposes of performing the provider's CIA reviews.

CIA Specific Training

Specific training usually addresses the requirements for coding and billing claims submitted to Federal health care programs. Specific training also may address other aspects of the individual's/entity's business operations that impact the Federal health care programs, such as cost reporting, contracting policies and procedures, and drug price reporting. Most CIAs require that the specific training include examples of proper and improper practices in the area that is the subject of the training. To the extent that the specific training relates directly to the subject matter of the CIA review, such specific training is likely to be significant/material to the subject matter of the CIA review and to result in the IRO auditing its own work as part of the CIA review. Therefore, an entity that provides CIA-mandated specific training likely would be precluded from performing a CIA review relating directly to the topic of that specific training. For example, an IRO

that provides specific training on how to correctly code and bill certain types of claims likely would be precluded from performing a CIA claims review involving the same type of claims addressed in the specific training.

Provider Staff Attending Training Seminars Presented by the IRO

If the primary content of the training seminar provided by the IRO is significant or material to the subject matter of the CIA review, then the IRO may be precluded from performing the CIA review as a result of provider staff attending a training seminar presented by IRO personnel.

However, if the information presented at the training seminar is very general (e.g., the training seminar involves IRO personnel making general remarks regarding relevant risk areas or presenting a variety of approaches to handling common issues/challenges as opposed to specific advice on a particular risk area), the fact that provider staff attend this training seminar likely would not preclude the IRO from performing CIA reviews for the provider, because the training likely would not have a significant/material impact on the CIA reviews.

Question: If the IRO performs specific compliance services for the provider (e.g., creates compliance policies, operates the compliance hotline, screens ineligible employees and contractors), can the IRO also conduct the CIA reviews?

Each type of compliance service must be individually analyzed.

IRO Developing the Provider's Policies and Procedures

If the provider implements policies and procedures that are developed for the provider by the IRO and those policies and procedures relate to the risk areas that are the subject of the CIA reviews, then the IRO likely would be precluded from performing the CIA reviews, for two reasons. First, if the IRO develops policies and procedures for the provider that relate to the risk areas that are the subject of the CIA reviews, then the IRO is making management decisions for the provider (e.g., directing specific aspects of the provider's operations). Second, the information contained in such policies and procedures would likely be significant/material to the CIA reviews.

IRO Operating the Provider's Hotline/Confidential Disclosure Program

This analysis depends on the IRO's involvement in the operations of the hotline/confidential disclosure program. If the IRO simply performs routine tasks, such as answering the phone, transcribing the allegations, and/or maintaining the confidential disclosure log, then this arrangement likely would not preclude the IRO from also

performing the CIA reviews, because the IRO is not auditing its own work or making management decisions.

However, if the IRO participates in any form of decision-making relating to the compliance hotline, such as substantiating the allegations, determining which allegations should be passed on to management, or resolving the allegations, then the IRO likely would be precluded from also performing the CIA reviews.

IRO Screening for Ineligible Persons

Again, this analysis depends on the specific role the IRO plays in carrying out this compliance service. If the IRO simply performs a mechanical task, such as entering the names into the screening databases, then this function likely would not impair the IRO's independence for purposes of performing the CIA reviews.

However, if the IRO participates in any form of decision-making, such as determining the provider's course of action when an individual or entity has been identified as ineligible, the IRO likely would be precluded from performing the CIA reviews, because the IRO is in the position of making management decisions for the provider.

Question: If the IRO evaluates the provider's existing compliance program before the provider's CIA is executed (e.g., performs a benchmarking review to compare the provider's compliance program to that of other providers in the same industry, or the OIG's compliance program guidance, to identify strengths and weaknesses in the provider's compliance systems), can the IRO perform the provider's CIA reviews?

The most relevant consideration in this situation is whether the IRO is involved in performing a management function or making management decisions for the provider. If the IRO's evaluation of the provider's existing compliance program results only in the IRO presenting its conclusions regarding the strengths and weaknesses of the provider's existing compliance program and making recommendations regarding areas for improvement, then this likely would not impair the IRO's independence for future CIA reviews. In that case, the provider's management would be responsible for evaluating the recommendations made by the IRO and designing and implementing any corrective action taken in response to the IRO's recommendations.

However, if the IRO is engaged to implement its own recommendations and corrective action relating to the strengths and weaknesses of the provider's compliance program, the IRO would be performing a management function or making management decisions for the provider and the IRO's independence for purposes of the CIA reviews likely would be impaired.

Question: If, prior to the execution of the provider's CIA, the IRO conducts a process review or internal controls review to identify strengths and weaknesses in the provider's compliance systems associated with specific risk areas that are addressed in the provider's CIA, can the IRO perform the provider's CIA reviews?

Again, the key issue is whether the IRO is making management decisions or performing management functions in connection with these pre-CIA reviews. If the IRO assesses the strengths and weaknesses of and recommends improvements to the provider's processes or internal controls related to specific risk areas subsequently addressed in the provider's CIA, but the provider's management is ultimately responsible for evaluating the IRO's recommendations and implementing any corrective action, the IRO's independence likely would not be impaired for purposes of future CIA reviews.

However, if as a result of the IRO's process review or internal controls review, the IRO is engaged by the provider to establish and implement new processes or internal controls that are directly related to the risk areas subject to audit under the provider's CIA, the IRO likely would not be independent for purposes of conducting future CIA reviews related to those risk areas. In that case, the IRO would be performing management functions or making management decisions for the provider and likely would be auditing its own work as part of the CIA reviews.

Question: If the IRO furnishes personnel to assist the provider's internal audit department in performing reviews, either before or after the execution of the provider's CIA, can the IRO also perform the CIA reviews?

The overarching principles that must be considered in this circumstance are whether the IRO is (i) making management decisions or performing management functions for the provider or (ii) auditing its own work as part of the CIA reviews. If the IRO's assistance to the provider's internal audit department is limited to providing personnel to perform work plan procedures that are developed by the provider's internal audit department and are not related to the subject matter of the CIA reviews, then the IRO's independence likely would not be impaired for purposes of future CIA reviews. However, if the provider were to outsource its internal compliance audit function to the IRO, either before or after the execution of the provider's CIA, the IRO's independence likely would be impaired for purposes of conducting the provider's CIA reviews. This is the case because internal audit is a management function and the outsourcing of the internal compliance audit function likely would result in the IRO auditing its own work as part of the CIA reviews.

Question: Can an IRO perform a provider's CIA reviews as well as serve as a resource for the provider's internal audit department (e.g., reviewing and commenting on work plans developed by the internal audit department to review specific compliance issues; reviewing an annual internal audit work plan developed by the provider and furnishing input on whether the internal audit department has adequately identified the provider's current risk areas, etc.)?

An IRO's independence for purposes of performing a provider's CIA reviews likely would not be impaired by the IRO advising the provider's internal audit department regarding reviews or audits conducted by the internal audit department during the term of the CIA, so long as the IRO does not dictate the areas subject to audit by the provider's internal audit department (the IRO would be making management decisions for the provider) or the provider does not outsource its internal audit department to the IRO (the IRO would be performing a management function for the provider and likely would be auditing its own work during the CIA reviews).