

## **CORPORATE INTEGRITY AGREEMENTS: IRO REVIEW OF UNALLOWABLE COSTS**

A Corporate Integrity Agreement (CIA) outlines the obligations an entity agrees to as part of a civil settlement with the Office of Inspector General (OIG) in exchange for avoiding exclusion from participation in Medicare, Medicaid or other Federal health care programs. The CIAs have common elements, but each one is tailored to address the specific facts of the case. CIAs require that the settling entity contract with an Independent Review Organization (IRO) to conduct verification reviews of specified areas, dependent on the nature of the terms of the Agreement. For the most part the IRO is charged with validating that the terms of the CIA are being met.

The scope of work of the IRO in most cases includes a review of Cost Reports to determine whether Unallowable Costs were included as part of reimbursement by federally financed health care programs. What that basically means to the provider is that it will not be permissible to include costs incurred as a result of the governmental investigation in a cost report or any other report that results in payment by the government. Given these ex-post facto possibilities, any organization that is the subject of an investigation that may ultimately lead to a settlement with the government, should give consideration to the potential ramifications a settlement may have, even before agreeing to its terms. This is particularly important with regards to Cost Report compliance requirements.

A typical Corporate Integrity Agreement says the following about unallowable costs. Note: the name of the particular organization in this case was redacted.

“The IRO shall conduct a review of \_\_\_\_\_ compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether \_\_\_\_\_ has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from the United States, or any state Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by \_\_\_\_\_ or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.”

A standard settlement agreement defines “Unallowable costs” as those costs incurred in connection with:

- Matters covered by the settlement agreement
- Federal Government audit and civil investigation of matters covered by the CIA
- Provider's investigation, defense, and corrective actions undertaken in response to the audit and civil investigation covered by the CIA including attorney's fees
- Negotiation and performance of the settlement agreement
- Payment by the provider pursuant to the agreement
- Any payments that are made to the relator including costs and attorneys' fees
- Costs of retaining an IRO and for preparation of reports to the OIG HHS.

Among the complicating matters is the fact that the investigation and settlement process may take a considerable amount of time to complete—sometimes well in excess of a year and in some cases several years. During this time, the organization continues to operate and submit required reports as part of its normal business cycle. Failing to take into consideration what costs may be found unallowable, can lead to problems later. The following are some useful tips to consider:

1. It is important to determine the starting point for incurring costs that would be defined as unallowable under a CIA. According to the OIG, this is when the organization first became aware of the issue that resulted in an investigation. Please note that the starting point would not be when the matter was disclosed to the government or the government made notification of an investigation. For example, if you received a hotline call that first identified the matter, the date of that call is your starting point. Any costs incurred on or after that date need to be identified and segregated.
2. Take steps to understand what costs must be excluded from the cost reports submitted to the government. When queried, OIG staff informed us that only direct external costs that were incurred in connection with the investigation and settlement, such as expenditures for outside services by legal counsel, accounting firms, and consultants should be excluded. It would not be necessary to account for and exclude the cost of internal staff time, e.g. internal audit, finance, Compliance Office, inside legal counsel's time, CEO's time, etc.
3. Take immediate steps to exclude the unallowable costs from the cost report. The easiest way is probably to assign the costs to a cost center that does not distributable to a government cost report.
4. Get advice about these matters as soon as it becomes apparent that things may move to a CIA. When confronted with the specter of an investigation, entities will naturally want to focus on the matters at hand—the specific allegations, identifying those who are involved, potential damage and strategy going forward. However, it would be a mistake to forget obtaining advice on how to treat financially the costs associated with the investigation.
5. As soon as it becomes apparent that a matter may ultimately lead to a settlement, it is advisable to maintain a file with documentation that evidences that the unallowable costs were in fact NOT included in the cost reports. Considering that an

investigation and ultimate settlement may drag out over a long period time, having maintained this separate set of documents evidencing that related costs were in fact segregated from the cost reports will save a lot of trouble and costs later. If done properly and thoroughly, it will be a lot easier and far less costly for the eventual IRO to conduct its review when the CIA goes into effect. Those organizations that fail to keep separate, complete records may find they have complicated their affairs greatly. In some cases individuals knowledgeable about the investigation costs leave or documentation goes astray. Organizations may even change financial systems. Without adequate foresight and preparation the internal staff charged with finding or recreating the necessary evidence may have a very difficult time completing their tasks. It will save a lot in terms of internal and external costs if adequate files are maintained from the beginning.

6. If the CIA requires IRO review of all Unallowable Costs, it is important to remember that it is a review of the evidence and not an audit of the Cost Reports. CIAs don't require an audit of the Cost Reports, only verification that they do not include Unallowable Costs. As such, the scope of the IRO work should be carefully limited to that objective. To do otherwise would invite an overly costly and unnecessary audit review.

Getting through a government investigation and ultimately a settlement can be very traumatic to the organization. And the strain on the staff who have to deal with the matters at hand including responding to government requests and demands and ensuring that the terms of the settlement are being met can be significant. With a little planning and foresight the process can be somewhat more palatable and potentially a lot less costly.

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